National Assembly for Wales
Health and Social Care Committee

Human Transplantation (Wales) Bill

Stage 1 Committee report

March 2013

Cynulliad
Cenedlaethol
Cymru

National
Assembly for
Wales

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National Assembly for Wales

Health and Social Care Committee

The Committee was established on 22 June 2011 with a remit to examine legislation and hold the Welsh Government to account by scrutinising expenditure, administration and policy matters encompassing: the physical, mental and public health of the people of Wales, including the social care system.

Current Committee membership

Mick Antoniw*
Welsh Labour
Pontypridd

Vaughan Gething**
Welsh Labour
Cardiff South and Penarth

Rebecca Evans
Welsh Labour
Mid and West Wales

William Graham
Welsh Conservatives
South Wales East

Elin Jones
Plaid Cymru
Ceredigion

Darren Millar
Welsh Conservatives
Clwyd West

Lynne Neagle
Welsh Labour
Torfaen

Lindsay Whittle
Plaid Cymru
South Wales East

Kirsty Williams
Welsh Liberal Democrats
Brecon and Radnorshire

During the Committee's consideration of its draft report, the Chair, Mark Drakeford AM, was appointed as the Minister for Health and Social Services. The Committee elected temporary Chairs for the remainder of its consideration of its draft report.

Mark Drakeford
Welsh Labour
Cardiff West

* Elected temporary chair for the meeting of 18 March 2013.

** Elected temporary chair for the meeting of 19 March 2013.

Contents

Summary of Recommendations

The Committee's recommendations to the Minister are listed below, in the order in which they appear in this report. Please refer to the relevant pages of the report to see the supporting evidence and conclusions:

General Principles of the Bill

The majority of us were content with the principle of deemed consent, and its introduction in Wales via the Bill. (Page 34, Paragraph 100)

Two members of the Committee, Darren Millar AM and William Graham AM, did not support the introduction of a system of deemed consent for organ donation in Wales. (Page 34, Paragraph 101)

Infrastructure and capacity

Recommendation 1
We recommend that, before the end of Stage 2 proceedings, the Minister prepare and publish a detailed plan for the future of critical care capacity in Wales, including resource implications, the timescales for any developments in this area, and how these matters will relate to the Bill. (Page 44, Paragraph 145)

Recommendation 2
In the event that the Bill results in a greater than anticipated increase in organ donor numbers, we recommend the Minister prepare a contingency plan in order to be able to respond to this. (Page 45, Paragraph 146)

Consent and the role of the family

Recommendation 3
We recommend the Minister make a definitive statement in advance of Stage 2 proceedings, clarifying his position in relation to the role of the family in a deemed consent system. (Page 72, Paragraph 267)

Recommendation 4
We note the Minister's evidence that, in practice, people whose next of kin cannot be found will not have their consent deemed. However we understand that, under the current system, it may be possible to proceed with donation in certain circumstances where family members

cannot be found, albeit with some conditions imposed on that donation. We recommend that the Minister clarifies why it is not the intention for this approach to continue under any new system. (Page 72, Paragraph 270)

Appointed representatives

Recommendation 5

We recommend the Minister clarify how, in practice, clinicians will be expected to ascertain whether a person has appointed a representative to deal with the issue of consent after their death, if such appointment has not been noted on the Organ Donor Register. (Page 77, Paragraph 299)

Recommendation 6

We recommend the Minister consider making provision for the Organ Donor Register to record representatives appointed by persons wishing their consent to be deemed. (Page 78, Paragraph 300)

Recommendation 7

We consider the arrangements under the Human Tissue Act 2004 to be preferable, whereby a person in a qualifying relationship could be contacted where an appointed representative was unable to act, and we recommend that this continues in relation to the Bill. (Page 78, Paragraph 301)

Residency

Recommendation 8

We believe the Bill should recognise that there will be residents in Wales who are not here voluntarily, for example, prisoners and some armed forces personnel from outside Wales. We recommend the Minister give further consideration to this matter. (Page 83, Paragraph 322)

Recommendation 9

We have concerns in relation to the application of the Bill to students, particularly international students. We recommend the Minister give further consideration to this matter. (Page 83, Paragraph 324)

Registration system

Recommendation 10
Whilst noting the Minister's evidence that all three of her counterparts have accepted the principle of a single Organ Donor Register for the UK, we recommend the Minister provide more information regarding the discussions with the other UK governments on this matter. In particular, we seek assurances from the Minister that the preferred option of a single ODR is deliverable, as it is dependent on the agreement of the other governments within the UK. (Page 92, Paragraph 366)

Recommendation 11
We recommend the Minister provide further information on the estimated costs involved in developing and implementing a single Organ Donor Register, and what monetary contribution the Minister expects to receive from the other governments within the UK. (Page 92, Paragraph 367)

Recommendation 12
In relation to individuals being able to choose to donate some but not all of their organs when registering with the Organ Donor Register, we note that deemed consent will apply to all organs on the Organ Donor Register list. Any person wishing to donate certain organs will have to expressly opt in and then select those organs to donate from the available list. We recommend that, as part of the education and communications campaign to accompany the Bill, the Minister should ensure that this matter is clearly explained and that people are aware of the options available to them, including the option to record an appointed representative on the Organ Donor Register in cases of deemed consent. (Page 92, Paragraph 369)

Communication and education

Recommendation 13
We recommend the Minister provide more information in relation to his test that "in a deemed consent system individuals need to be fully aware of the need to consent or object to an action and be fully aware of the consequences" and, in particular, how he intends to meet that test. (Page 104, Paragraph 422)

Recommendation 14
We recommend the Minister give further thought to the level of funding required for such an extensive communication and education campaign. (Page 105, Paragraph 427)

Training

Recommendation 15
We believe that the Minister should satisfy himself that sufficient funding and resources are in place to ensure that effective training is provided for medical professionals in relation to any new system of deemed consent. Further to this, we recommend that the Minister provide confirmation of this in a revised Explanatory Memorandum following stage 2 proceedings. (Page 109, Paragraph 446)

Financial implications of the Bill

Recommendation 16
We note the Minister’s view that an increase in donor rates under the Bill would not incur additional costs for critical care and surgical services. In light of the evidence we have received, we are not convinced on this point and believe it would merit further consideration. We recommend the Minister prepare and publish a detailed plan of the resource implications of the Bill for the future of critical care capacity in Wales, and that he does so before the end of Stage 2 proceedings. (Page 116, Paragraph 475)

Novel forms of transplantation

Recommendation 17
We recommend that a list of organs to be excluded from deemed consent should be defined in regulations. Such regulations should be subject to consultation and Assembly oversight via the affirmative resolution procedure. (Page 126, Paragraph 522)

Research

Recommendation 18
We recommend that the communications programme to accompany the Bill should include information about the use of organs for research and should inform people that they need expressly to opt in to the ODR if they wish their organs to be available for research. (Page 127, Paragraph 529)

The application of the Bill to living persons

Recommendation 19
We believe there is merit in the views raised by the NHS Blood and Transplant that, to avoid confusion, the Bill should not make provision in respect of living donors and we recommend that the Human Tissue Act 2004 should remain the legal basis for such donations. (Page 129, Paragraph 534)

Code of practice

Recommendation 20
Given the importance of the Code of Practice in providing guidance on the provisions and implementation of the Bill, we welcome the Minister's commitment to provide us with sight of the draft Code in advance of Stage 3 proceedings. We expect to receive this before the end of Stage 2 proceedings in order for us to be able to consider it fully in preparation for Stage 3. Further to this, we recommend that, when the Minister shares the draft Code with us, he also makes it publicly available. (Page 132, Paragraph 549)

Recommendation 21
We note that the Bill, as currently drafted, provides for the Code of Practice to be laid before the Assembly (we welcome this) and be subject to the negative resolution procedure. Again, given the significance of the Code, we recommend that, once laid, it should be subject to the affirmative resolution procedure. (Page 132, Paragraph 550)

Evaluation of the Act

Recommendation 22
We recommend that any change in the legislative arrangements for consent should be accompanied by a robust evaluation strategy, which would provide both the means of measuring the success of such a change and a clear evidence base for policy decisions elsewhere. (Page 136, Paragraph 566)

Glossary

AM	Assembly Member
ARCW	Academy of Royal Colleges Wales
BMA	British Medical Association
BME	Black and Minority Ethnic
BTS	British Transplantation Society
CLOD	Clinical Lead for Organ Donation
DBD	Donation after Brain Death – DBD may take place where death is confirmed following neurological tests to establish whether the patient has any remaining brain function. Patients declared brain dead may have suffered head trauma, for example in a car accident, or a massive stroke. These patients are sometimes also called "heart-beating donors" because the circulatory system is maintained through a ventilator whilst consent is established and until the donation takes place.
DCD	Donation after Circulatory Death – DCD may take place following diagnosis of death by cardio-respiratory criteria. These patients are called "non heart-beating donors" because death follows the cessation of the body's cardio-respiratory functions. DCD may be either "controlled" which describes organ retrieval which follows the planned limitation or withdrawal of treatment at the end of a critical illness from which the person will not recover; or "uncontrolled" which occurs following a sudden, irreversible cardiac arrest. Uncontrolled DCD is rare in the UK at present.
ECHR	European Convention on Human Rights
EM	Explanatory Memorandum
HTA	Human Tissue Authority
LHB	Local Health Board
NHSBT	NHS Blood and Transplant

NICE	National Institute for Health and Clinical Excellence
ODR	Organ Donor Register
ODTF	Organ Donation Task Force
Organs	In this report, where the terms ‘organs’, ‘organ donation’ or ‘donation’ are used, this means organ and tissue donation, unless the context suggests otherwise
QALY	Quality Adjusted Life Year – the number of QALYs gained from a transplant is calculated by comparing the health state of a transplant patient with the health of a patient receiving medical care (for example, dialysis) on a number of dimensions such as mobility, lack of pain/discomfort, ability to self-care, anxiety/depression and capacity to carry out ‘usual activities’. A year of ‘perfect’ health is worth one QALY.
RCN	Royal College of Nursing
RIA	Regulatory Impact Assessment
SNOD	Specialist Nurse for Organ Donation
UKDEC	UK Donation Ethics Committee

Donation rates: summary

1. The Explanatory Memorandum states that over 30,000 people die in Wales every year and in 2011/12 there were around 250 potential donors. Of these potential donors, 67 became organ donors in Welsh hospitals.

2. The Explanatory Memorandum goes on to state that the introduction of an opt-out system could result in a 25 to 30 per cent increase in deceased organ donation rates which could equate to a further 15 donors each year in Wales.

3. Each of these 15 donors, on average, might donate 3 organs resulting in around 45 more organs becoming available to the UK pool for transplantation.

4. The Explanatory Memorandum recognises that it is likely a large proportion of additional organs donated by residents in Wales could be transplanted into residents living in other parts of the UK. It is estimated that over a four year period (based on data from 2008-11) just over 30 per cent of organs donated by people in Wales are transplanted into people living in Wales.[1]

5. The following tables show the percentage of the population registered on the organ donor register (ODR) (Table 1), the total number of deceased donors (Table 2) and the total number of patients on the transplant waiting list (Table 3) for each UK region since 2008/09. Table 4 shows the demographic characteristics of organ donors in the UK from 1 April 2011 to 31 March 2012.

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[1] Explanatory Memorandum (EM), page 41, paragraph 129

Table 1

	Percentage of population registered on ODR			
	2008/09	2009/10	2010/11	2011/12
England	26	27	28	29
Northern Ireland	26	26	27	29
Scotland	32	34	36	39
Wales	27	30	31	31

Source: NHS Blood and Transplant, Organ Donation and Transplantation Directorate

Table 2

	Total deceased donors				
	2008/09	2009/10	2010/11	2011/12	% increase since 2008/09
England	769	830	835	896	16.5
Northern Ireland	21	18	40	39	85.7
Scotland	72	63	67	81	12.5
Wales	35	41	66	67	91.4

Source: NHS Blood and Transplant, Organ Donation and Transplantation Directorate and Research Service calculations

Table 3

	Total number of patients on transplant waiting list*				
	At 31-Mar-09	At 31-Mar-10	At 31-Mar-11	At 31-Mar-12	% decrease since March 09
England	6,541	6,703	6,597	6,471	-1.1
Northern Ireland	257	230	210	222	-13.6
Scotland	653	651	627	597	-8.6
Wales	372	338	309	284	-23.7

* Patients on transplant waiting list are based on the postcode of residence and excludes patients temporarily suspended from the transplant list

Source: NHS Blood and Transplant, Organ Donation and Transplantation Directorate and Research Service calculations

Table 4

		Demographic characteristics of organ donors in the UK, 1 April 2011 - 31 March 2012	
		Total number	Total percentage
Age	0-17	43	4
	18-49	411	38
	50-59	267	25
	60-69	250	23
	70+	117	11
Cause of death	Intracranial	914	84
	Trauma	66	6
	Other	108	10
Ethnicity	White	1,042	96
	Asian	16	1
	Black	12	1
	Other	18	2

Source: NHS Blood and Transplant, Organ Donation and Transplantation Directorate

1. Introduction

Background

6. At its meeting on 20 November 2012, the Assembly's Business Committee agreed to refer the Human Transplantation (Wales) Bill[2] ("the Bill") to the Health and Social Care ("the Committee") for consideration of the general principles (Stage 1), in accordance with Standing Order 26.9. The Business Committee agreed that the Committee should report to the Assembly by 22 March 2013.

7. On 3 December 2012, the Minister for Health and Social Services, Lesley Griffiths AM ("the Minister"), introduced the Bill and made a statement[3] in plenary the following day.

Terms of Reference

8. The Committee agreed the following terms of reference for its Stage 1 scrutiny:

> To consider the general principles of the Bill and the need for legislation to increase the number of organs and tissues available for transplant by introducing a soft opt-out system of organ and tissue donation in Wales, by reference to:
>
> 1. The individual provisions set out in the Bill—
>   - Section 2, relating to the promotion of transplantation,
>   - Section 3, relating to lawful transplantation activities,
>   - Sections 4-8, relating to consent,
>   - Sections 9-11, relating to offences,
>   - Sections 12-20, which make general provision.
> 2. Any potential barriers to the implementation of these provisions and whether the Bill takes account of them.
>
> 3. Whether there are any unintended consequences arising from the Bill.

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[2] Human Transplantation (Wales) Bill, available at: http://www.senedd.assemblywales.org/mgIssueHistoryHome.aspx?IId=5178

[3] Record of Proceedings (ROP), 4 December 2012, available at: http://www.assemblywales.org/bus-home/bus-chamber-fourth-assembly-rop.htm?act=dis&id=241217&ds=12%2F2012#04
(NB: unless otherwise stated, subsequent references in this report to ROP refer to the proceedings of the Health and Social Care Committee)

4. The financial implications of the Bill (as set out in Part 2 of the Explanatory Memorandum (the Regulatory Impact Assessment), which estimates the costs and benefits of implementation of the Bill).

5. The appropriateness of the powers in the Bill for Welsh Ministers to make subordinate legislation (as set out in Part 1, paragraph 90 of the Explanatory Memorandum, which contains a table summarising the powers for Welsh Ministers to make subordinate legislation).

The Committee's approach to evidence gathering

9. On 6 December 2012, the Committee launched a call for written evidence based on its agreed terms of reference. A link to the responses that we received and were authorised to publish is available at Annexe A.

10. The Committee also took oral evidence from a number of witnesses; a schedule of oral evidence sessions is attached at Annexe B.

11. In reporting on the Bill, the Committee has taken account of the views of all those who gave evidence to it and have sought to reflect the key issues raised in evidence.

12. The Committee would like to thank all those who took the time to respond to its call for evidence and assist with its work.

13. During the Committee's consideration of its draft report, the Chair, Mark Drakeford AM, was appointed as the Minister for Health and Social Services. The Committee elected temporary Chairs for the remainder of its consideration of its draft report. While Lesley Griffiths AM was the Minister who gave evidence to the Committee, and references in this report to evidence from the Minister refer to evidence from her, our recommendations are addressed to the new Minister, Mark Drakeford AM, who will now be responsible for the Bill.

2. Background

Legislative Competence

14. The principal powers enabling the Assembly to make a Bill in relation to consent of the removal, storage and use of organs and tissues for the purpose of transplantation are contained in Subject 9 (Health and health services) of Schedule 7 to the Government of Wales Act 2006.

Aims of the Bill

15. The Explanatory Memorandum accompanying the Bill states:

> "The Human Transplantation (Wales) Bill prescribes how consent is to be given in Wales to the removal, storage and use of human organs and tissues for the purpose of transplantation. The Bill covers the donation of organs and tissues for transplantation both from deceased and living donors. In relation to deceased donation, it gives effect to the Welsh Government's commitment to introduce a soft opt-out system of organ and tissue donation in Wales."[4]

16. It goes on:

> "A soft opt-out system is one where consent to the removal and use of organs and tissues for transplantation is deemed as having been given unless the deceased objected during their lifetime, and where the next of kin will be involved in the decision making process. The overarching aim of the Bill is to increase the number of organs and tissues available for transplant, which will benefit the people of Wales by reducing the number of people dying whilst waiting for a suitable organ to become available and improving the lives of others."[5]

17. In respect of the application of the Bill, the Explanatory Memorandum states:

> "The effect of this Bill will be to introduce, for people over the age of 18 who both live and die in Wales, a concept called

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[4] Explanatory Memorandum (EM), page 1, paragraph 1

[5] Ibid.

> deemed consent. Deemed consent will exist alongside express consent as one of the ways in which a person can give their consent to the donation of organs for transplantation."[6]

18. It continues:

> "People will be given the opportunity of taking an express decision, for example to formally "opt out" of organ donation by placing their name on a register. But if they choose not to do so, despite having had the opportunity, then they will be treated as though they had no objection to being a donor (or in other words their consent will be deemed)."[7]

19. Provision is made for persons standing in a 'qualifying relationship'[8] to the deceased to be involved in the decision making process. It is anticipated that the wishes of the deceased, whether through deemed or express consent, will be made known to a person in a qualifying relationship as part of discussions.

20. Wales will continue to share a transplant waiting list with the rest of the UK and organs will be allocated on the basis of clinical need and suitable match.

Policy objectives

21. The Explanatory Memorandum states:

> "In Wales, around three people a month died while waiting for an organ transplant in 2011/12. Around 300 people in Wales at any one time are on the active waiting list for a transplant."

22. Only a small number of people die in circumstances where they are able to donate their organs. This is normally where the deceased is on a ventilator in a hospital intensive care unit.[9]

23. The Explanatory Memorandum continues:

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[6] EM, page 8, paragraph 12

[7] Ibid.

[8] Section 17(2) of the Bill makes provision for a 'qualifying relationship'. This is explored further in Chapter 5.

[9] EM, page 7, paragraph 8

> "To put this into context, over 30,000 people die in Wales every year, and in 2011/12 there were around 250 potential donors. However, only 67 of those people became organ donors in Welsh hospitals."[10]

24. The Explanatory Memorandum goes on to say that introducing an opt-out type system could result in a 25 to 30 per cent increase in deceased organ donation rates, which could equate to a further 15 donors each year in Wales, each of whom on average could donate three organs. It states that this would mean that around 45 more organs could become available to the UK pool for transplantation.[11]

Existing legislative provisions

25. In relation to the existing legislative provisions in this area, the Explanatory Memorandum states:

> "The Bill sets out in one place the main provision relating to consent for transplantation activities in Wales. However, in order to maintain an effective cross-border regime in terms of the operation of the UK-wide organ transplantation programme, there is an inevitable interplay with the Human Tissue Act 2004 (the 2004 Act), which is the current legislative framework for England, Wales and Northern Ireland."[12]

26. It goes on:

> "As a result, the Bill restates, for Wales, certain sections of the 2004 Act directly related to consent for the purposes of transplantation. However, certain other provisions of the 2004 Act not directly related to consent have not been restated but continue to apply in Wales, for example, provisions relating to the Human Tissue Authority (…). In most respects the Welsh Government has no intention of changing the settled law in this area; the main change brought about by the Bill is to introduce the concept of deemed consent."[13]

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[10] EM, page 7, paragraph 8

[11] EM, page 12, paragraph 21

[12] EM, page 5, paragraph 2

[13] Ibid.

Policy context

27. The Explanatory Memorandum states that, following a comprehensive review of organ donation in the UK, the Organ Donation Taskforce (ODTF) produced its report entitled 'Organs for Transplants' in January 2008. The report made 14 recommendations that would contribute to the aim of improving the funding of organ donation, improving the associated infrastructure, and increasing organ donation rates by 50 per cent within five years.

28. Since the publication of the ODTF report, we note that from 2008-09 to 2011-12, the number of organ donations in Wales has increased from 35 to 67 donors, which equates to a 91.4 per cent increase.

29. The Explanatory Memorandum goes on to state that "The Wales Organ Donation Implementation Group (WODIG) was set up to ensure the recommendations were implemented in Wales."[14]

30. In November 2008, the Organ Donation Taskforce published a further report; 'The potential impact of an opt-out system for organ donation in the UK'. The Explanatory Memorandum notes:

> "This report recommended against the introduction of an opt-out system at that time, preferring instead to concentrate effort on improvements to the current arrangements, but recommended reviewing the position after five years."[15]

31. The issue of presumed consent for organ donation was widely debated during the third Assembly (2007-11). The Health, Well-being and Local Government Committee conducted an inquiry into presumed consent for organ donation in 2008 and published a report[16] of its findings and recommendations in July 2008.

32. In its report, the Health, Well-being and Local Government Committee concluded:

> "The most urgent and productive steps for improving donation rates rest with the early implementation in Wales of the UK Organ Donation Task Force (ODTF) recommendations. We do

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[14] EM, para 13-14

[15] EM, para 15

[16] National Assembly for Wales, Health, Well-being and Local Government Committee, Inquiry into presumed consent for organ donation, July 2008

> not rule out introducing presumed consent in Wales at some point in the future. However, we do not believe that it is currently the most urgent priority and believe that it could be a distraction from other, more productive actions."[17]

33. In a written response to the Committee's recommendation, the then Minister for Health and Social Services, Edwina Hart AM, stated:

> "The Assembly Government considers that the Committee's report does not reflect adequately the evidence it received on the strength of opinion in relation to presumed consent nor does the report acknowledge some of the actions already announced in relation to organ donation and transplantation by the Welsh Assembly Government."[18]

34. Between October 2008 and January 2009, the then Minister for Health and Social Services, Edwina Hart AM, initiated a public debate to capture opinion on whether Wales should become the first UK country to introduce an opt-out system. The Welsh Government then launched a public consultation on the issue, entitled 'Options for Changes to the Organ Donation System in Wales'[19], in May 2009 and published a consultation report[20] based on submissions received in September 2009. The report stated that "the majority of responses supported a change to the organ donation consent system in Wales to a soft opt-out system".[21]

35. In January 2011, the Welsh Government introduced the proposed National Assembly for Wales (Legislative Competence) (Health and Health Services) Order 2011[22] (the proposed Order), which sought to transfer legislative powers in relation to organ donation from Westminster to the National Assembly. The proposed Order was subsequently withdrawn by the Welsh Government following the 'Yes'

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[17] National Assembly for Wales, Health, Well-being and Local Government Committee, Inquiry into presumed consent for organ donation, July 2008

[18] National Assembly for Wales, Health, Well-being and Local Government Committee, Inquiry into presumed consent for organ donation, The Minister's Response, September 2008

[19] Welsh Government, Consultation Paper - Options for changes to the organ donation system in Wales, May 2009

[20] Welsh Government, Consultation Report – Options for changes to the organ donation system in Wales, September 2009

[21] Ibid

[22] The National Assembly for Wales (Legislative Competence) (Health and Health Services) Order 2011)

vote in the March 2011 referendum on further powers for the National Assembly for Wales.

Welsh Government consultation

36. Prior to the publication of the Bill, the Minister published a White Paper on proposals for legislation on organ and tissue donation in November 2011[23]. The consultation on the White Paper ran until 31 January 2012. There were 1,234 responses received.

37. This was followed, in June 2012, by publication of the draft Human Transplantation (Wales) Bill, along with a draft Explanatory Memorandum and Consultation Document.[24] The consultation on the draft Bill ran until September 2012. In October 2012, the Welsh Government published a summary of the responses.[25] The consultation received 2,977 responses.[26]

38. As part of the Wales Omnibus Survey[27], the Welsh Government commissioned the collection of data based on questions included as part of the survey during the period between June 2012 and June 2016.

39. As part of the first wave of the survey ('the Baseline survey') conducted in June 2012, 1,006 people aged 16 and over were asked questions about organ donation. Around half of respondents (49 per cent) were in favour of changing to an opt-out system of organ donation, while less than a quarter were against (22 per cent). A further 21 per cent said they needed more information to decide and 8 per cent said they did not know.[28]

40. The Baseline Survey report, published in October 2012[29], "presents baseline findings from which changes in public attitudes,

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[23] Welsh Government, Proposals for Legislation on organ and tissue donation: A Welsh Government White Paper, November 2011

[24] Welsh Government, draft Human Transplantation (Wales) Bill and draft Explanatory Memorandum and Consultation Document, June 2012

[25] Welsh Government, draft Human Transplantation (Wales) Bill and draft Explanatory Memorandum and Consultation Document, Summary of Responses, October 2012

[26] Welsh Government – Summary of responses, Draft Human Transplantation (Wales) Bill and Explanatory Memorandum: Consent to organ and tissue donation in Wales, 3 December 2012

[27] Wales Omnibus Survey

[28] Ibid.

[29] Welsh Government, Public Attitudes to Organ Donation: Baseline Survey 2012, October 2012

awareness and understanding of the organ donation system can be monitored. The analysis will also be used to inform how communications are targeted among different groups of the population."[30]

Changes to the Bill following consultation

41. The Explanatory Memorandum states that:

> "Two consultations have assisted with the drafting of the legislation and a number of areas have been clarified as a result. In particular, the Bill has been refined to provide clearer provision relating to people who lack capacity and the role of qualifying relations and appointed representatives in the donation process."[31]

42. It continues:

> "The Bill has been further refined in terms of different processes to be followed for deceased and living donation. There have also been a number of drafting changes in relation to the interplay with the 2004 Act."[32]

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[30] Welsh Government, Public Attitudes to Organ Donation: Baseline Survey 2012, October 2012
[31] EM, page 33, paragraph 90
[32] Ibid.

3. General principles and the need for legislation

The introduction of a system of deemed consent for organ donation in Wales

43. In response to our call for written evidence, we received over 200 written responses from organisations and individuals. In addition, we heard oral evidence from 17 witnesses.

44. All the evidence we received expressed support for the aspiration of increasing organ donation rates in Wales.

45. A number of organisations expressed support for the introduction of the Bill, including the Kidney Wales Foundation, the British Heart Foundation, the British Medical Association Cymru Wales (BMA Cymru Wales), the National Kidney Foundation, the Welsh Kidney Patients Association (WKPA), the Cystic Fibrosis Trust and the Clinical Lead for Organ Donation (CLOD) in Cwm Taf Health Board.

46. The main reasons for this support included:

- a belief that it would lead to an increase in the number of organs available for transplantation;
- that more lives would be saved under an opt-out system;
- the success of similar approaches in other countries;
- that other measures to increase organ donation had been exhausted.

47. However, the majority of respondents to our call for written evidence did not support the principle of a deemed consent system for organ donation. These included the Bench of Bishops of the Church in Wales, the Catholic Bishops of Wales, the Royal College of Nursing (RCN) Wales, the Anscombe Bioethics Centre, the Society for the Protection of Unborn Children (SPUC) and Patient Concern. In addition, a number of members of the public contacted us to register their objections to the Bill.

48. Among the main reasons for opposing introduction of the Bill were:

- that deeming consent for the removal of organs for transplantation would mean that donation could no longer be considered to be a 'gift';
- that this would constitute the state "taking organs without explicit consent";
- concerns that changing the system to deemed consent could inadvertently result in a decrease in the number of organs available for transplantation if people were to remove themselves from the organ donation register (ODR) in protest against the change in the law;
- that the money set aside for the implementation of the Bill could be better used in other ways to increase donations rates, such as a comprehensive education and communication programme.

Evidence from respondents in support of the Bill

49. A number of witnesses stated that they were content with the principle of deemed consent and suggested that the Bill had the potential to lead to an increase in donation rates.

50. The Kidney Wales Foundation said they believed the measures set out in the Bill "are a progressive proposed change in the law and will be a key component of change in organ donation in the UK." [33]

51. They acknowledged that it was "key that the proposed legislation is implemented with the goodwill of the people of Wales. A transplant law provides only a legal environment which can influence the extent to which potential donors can be used. The law in proper practice, as evidenced by the Bill, will be essential." [34]

52. The Clinical Lead for Organ Donation (CLOD), Cwm Taf Health Board, Dr Dariusz Tetla, told us:

> "As a person who is actively involved in organ transplantation and donation issues I strongly support every initiative which would lead to an increase in the number of organ donations."
>
> "I hope that the new legislation would strengthen the foundation of organ transplantation in Wales, which was

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[33] Written evidence, HT(Org)25

[34] Ibid.

> established a few years ago after introduction Organ Donation Taskforce recommendations, and it would allow further increase in organ donation activity."[35]

53. Mr Phil Walton, a Specialist Nurse for Organ Donation (SNOD) based in Hywel Dda Local Health Board and Team Manager for organ donation services in south Wales, said:

> "I am really supportive of the fact that in Wales we are trying something brand new in the UK that is raising the profile of organ donation."[36]

54. He went on:

> "Knowing the team that I work in, and that works for me, we are supportive of the legislation, and we are quite happy to work alongside the Welsh Government to implement it if it comes through."[37]

Other measures to accompany the Bill

55. Other witnesses, whilst supportive in principle, qualified their support with a number of caveats and/or stated that extra measures would also be needed to accompany the Bill.

56. The British Heart Foundation told us they "strongly support" the introduction of a soft opt-out system, but they recognised that "legislation in itself is not a 'magic bullet' but rather a key facilitator which must be introduced alongside an organised infrastructure and increased public awareness for a soft opt-out system to succeed."[38]

57. The Cystic Fibrosis Trust said:

> "Whilst the emphasis to date has been on getting people to sign the national organ donation register, it is absolutely clear that unless other fundamental problems are also addressed, this will be of modest benefit."[39]

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[35] Written evidence, HT(Org)14

[36] RoP, paragraph 239, 20 February 2013, Health and Social Care Committee

[37] RoP, paragraph 291, 20 February 2013, Health and Social Care Committee

[38] Written evidence, HT(Org)21

[39] Written evidence, HT(Org)13

Practical issues around implementation

58. Despite offering their support for the principle of deemed consent and/or the Bill, a number of witnesses highlighted their concerns about the practicalities of implementing a system of deemed consent in Wales.

59. The BMA Cymru Wales told us they were "delighted" about the introduction of an opt-out system for organ donation in Wales, but:

> "(…) our preferred model is a standard form of soft opt-out as practised in other countries, rather than the combined opt-in/opt-out system proposed in the Bill."[40]

60. They said they had concerns that introducing a "hybrid system" carried some risks, including making the system too complicated to understand or explain to the public. [41]

61. NHS Blood and Transplant (NHSBT) said they were concerned that including references to living donation in the Bill could lead to misunderstanding and said they would "favour references to living donation being removed from the bill and the Human Tissue Act 2004 remain the legal basis of living donation in Wales."[42]

62. The UK Donation Ethics Committee (UKDEC) and the Nuffield Council on Bioethics both stated that they had no ethical objection to the principle of deemed consent.

63. The Nuffield Council on Bioethics told us that "deemed consent is not a sort of a poor man's consent—one has genuinely consented"[43], but that this was reliant on the communication plan being implemented thoroughly to assume that, if a person had not opted out, it was because they were aware and understood the Bill and supported the procedure. This opinion was echoed by the Human Tissue Authority (HTA).

64. However, the UKDEC and the Nuffield Council on Bioethics both expressed concerns about the practicalities of changing to an opt-out

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[40] Written evidence, HT(Org)18

[41] Ibid.

[42] Written evidence, HT(Org)5

[43] RoP, paragraph 283, 30 January 2013, Health and Social Care Committee

system, and the Nuffield Council on Bioethics noted some doubts as to the impact of such a change.

65. UKDEC told us they also had reservations about "the impact on the relationship between professionals and donor families, and on the confidence of professionals to explore new and ethically challenging techniques aimed at increasing the number of successful donations."[44]

66. Both UKDEC and the Nuffield Council on Bioethics highlighted the need for a programme of robust research to accompany the implementation of the Bill. [45]

67. In their evidence, the HTA said that any new system should not "add further complexity and that everyone involved in the process, including clinicians and the family, are informed fully of their role and responsibilities."[46]

Evidence from respondents opposed to the Bill

Donation as a gift

68. All faith groups that expressed a view to us said they supported the principle of organ donation but the majority did not support the introduction of a deemed consent system, mainly because they considered that donation under such circumstances could not be considered to be a gift.

69. On this point, the Catholic Bishops in Wales said:

> "If organs are taken without the prior, free and express consent of the deceased, or even against the express wishes of relatives, then it becomes organ transplantation but has ceased to be organ donation."[47]

70. Similarly, the Bench of Bishops of the Church in Wales said:

> "(…) a gift by definition is a voluntary donation by one person to another and therein lies the difficulty we have with this Bill. It assumes that if you have not opted out of organ donation,

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[44] Written evidence, HT(Org)4
[45] Written evidence, HT(Org)4 and HT(Org)8
[46] Written evidence, HT(Org)27
[47] Written evidence, HT(Org)3

> your organs can be used after death. We cannot see how a failure to opt out can be interpreted to mean consent to the transplantation of organs."[48]

71. The Muslim Council of Wales echoed this view:

> "(…) there is also an ethical concern about the way in which presumed consent will impact on organ donation itself, namely that it should be just that: a donation given freely and willingly by one individual for the direct benefit of another."[49]

72. The South Wales Jewish Representative Council told us:

> "(…) where organ donation after death is made in conformity with Jewish practice, the obligation ("mitzvah") to perform an act of "pikuach nefesh" (saving a life) rests with the family of the dead person and so a Jewish perspective is that presumed consent diminishes the altruistic gift essence of organ donation and is perceived to diminish the status and respect with which the body / body parts are held after death."[50]

73. Patient Concern and the Catholic Medical Association made similar points about the principle of donation as a gift.[51]

74. We heard evidence, however, that some faith groups had "discussed the Bill and come to a different outlook". Summarising this, Cytûn told us:

> "Within the Presbyterian Church of Wales's church in society department there has been considerable support for these measures (…) although, again, opinion is strong on both sides. The Religious Society of Friends—the Quakers—recently considered the ethical and practical implications of the Bill. They realised that not everyone will support the intentions of the Bill, feeling that an opt-in method, as currently available, best protects individual and communal sensibilities. However,

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[48] Written evidence, HT(Org)1

[49] RoP, paragraph 149, 7 February 2013, Health and Social Care Committee

[50] Written evidence, HT(Org)9

[51] Written evidence, HT(Org)6 and HT(Org)24

> overall, they feel that there is nothing to impede their support for the Bill (…).”[52]

75. The Methodist Church told us:

> “We do not have a fixed position as yet because we are a British church and this happening in Wales is triggering us to have to think ahead about our position elsewhere across Britain. However, we support the principle of organ donation and want to encourage it. We recognise the concerns that have been expressed clearly about the importance of gift and donation and the theological issue about presuming that there is a right to someone’s body after death.”[53]

Removal of organs without express consent

76. Other respondents suggested that legislation which gave effect to the principle of deemed consent in relation to organ donation would constitute the state “taking organs without explicit consent”.[54]

77. This was a particular concern for members of the public who responded to our consultation.

Unintended consequences – decrease in donation rates

78. Some respondents suggested that the introduction of the legislation could, unintentionally, result in a decrease in donation rates.

79. Again, this was of particular concern to members of the public who responded to our consultation. A number of respondents told us that they were so opposed to the principle of the legislation, that they would either consider removing their name from the organ donor register or would elect to opt out of any new system in protest.

80. The issue of possible unintended consequences of the legislation is addressed in more detail in Chapter 4.

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[52] RoP, paragraph 138, 7 February 2013, Health and Social Care Committee

[53] RoP, paragraph 163, 7 February 2013, Health and Social Care Committee

[54] Written evidence, HT(Org)20

More effective use of resources

81. Some respondents told us that, in their view, the resources set aside to implement the provisions of the Bill could be used more effectively in other ways to increase organ donation rates.

82. On this point, the Anscombe Bioethics Centre said:

> "The most ethical and effective course of action is to concentrate efforts on education, communication and restructuring which have led to and continue to lead to dramatic improvements in the rate of donation in Wales."[55]

Timing

83. Some respondents said that now was not the right time for legislation on this matter, as work on the ODTF recommendations was still on-going.

84. Indeed, the RCN told us that they did not favour a change to an opt-out system at present, but would consider if there was a need to change this position following the completion of the 5-year programme for the implementation of the ODTF recommendations.[56]

The effectiveness of the proposed legislation in increasing donation rates

85. Some respondents told us they were not convinced that the Bill would result in an increase in the number of organs available for donation.

86. On this point, Professor John Saunders told us that he was "broadly supportive of the Bill as drafted" and that he did "not have a problem with [deemed consent]. Non-consensual removal is justifiable in moral terms."[57]

87. However, he noted that:

> "The Bill has been introduced in the face of two expert inquiries: one UK wide which was unanimous despite starting

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[55] Written evidence, HT(Org)30

[56] Written evidence, HT(Org)15

[57] RoP, paragraphs 272-273, 7 February 2013, Health and Social Care Committee

> with divided opinions; and one in Wales with a 2:1 majority against. It is nowhere adequately explained why these two expert groups got it wrong."[58]

88. In his view, "there is nothing in the Explanatory Memorandum to the Bill to suggest that a further significant improvement can be achieved by this legislation."[59]

Provision for medical professionals to object to participation in the proposed system

89. The RCN said that some of their members had raised concerns relating to their involvement in donation processes in the proposed system.

> "These concerns were relevant to wider consideration of the possibility of an individual's 'conscientious objection' to participation in organ retrieval and transplantation… Regardless of an individual's specific reasons for wishing to be excluded from facilitating donation and transplant, it is an important matter of policy that such 'conscientious objections' (whether enduring, modifiable or perceived) should be anticipated, and that adequate guidance for the management of such eventualities should be provided for. It is essential that clinicians' duty of care in such circumstances is clearly defined in such guidance."[60]

90. The Society for the Protection of Unborn Children echoed this view.[61]

Evidence from the Minister

91. In outlining the purpose of the Bill, the Minister said:

> "On average, three people die every month in Wales while waiting for a transplant. We believe that a soft opt-out system will lead to a significant improvement in the prospects of people on waiting lists in the future. We know that transplant surgery extends lives, improves the quality of lives and is cost-

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[58] Written evidence, HT(Org)28

[59] Ibid.

[60] Written evidence, HT(Org)15

[61] Written evidence, HT(Org)20

> effective. Donor families find comfort in knowing that the death of a loved one provided such benefits to others."[62]

92. She said that it was also about:

> "(…) a change in societal attitude. We need to make organ donation the norm. We do not talk about it as much as we should. In the countries where we have seen soft opt-out systems or opt-out systems, you see that much more: it is part of normal society."[63]

93. She said that, despite the success to date in increasing the number of organs for transplantation, "(…) since I have been Minister for health—it is nearly two years now—the figure has stuck at around 31%. We do not seem to be able to budge above that. I have said before that not one thing will make the difference we want. I think that this Bill will help to make a big difference, but we need to look at the on-going communications campaign as well."[64]

94. The Minister told us that the policy behind the Bill was "evidence-based":

> "Studies have consistently shown that countries with opt-out systems for organ donation generally have higher rates of donation per head of population. It really is all about clarifying people's wishes. Research has also shown that families are much more likely to agree to organ donation when a loved one dies if they know what the deceased's wishes were. I know that you will want assurances about the safeguards that are in place."[65]

95. In terms of these safeguards, the Minister told us:

> "One main safeguard is our commitment to ensuring that everyone in Wales becomes aware of the new legislation and how it works. Our plans for a public-awareness campaign are absolutely unprecedented for publicity about organ donation in Wales. We are also committing ourselves to continuing

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[62] RoP, paragraph 276, 24 January 2013, Health and Social Care Committee
[63] RoP, paragraph 300, 24 January 2013, Health and Social Care Committee
[64] RoP, paragraph 177, 20 February 2013, Health and Social Care Committee
[65] RoP, paragraph 277, 24 January 2013, Health and Social Care Committee

> awareness raising into the future through a duty in the Bill to promote transplantation."[66]

Our view

Responses from the public

96. We recognise that the subject matter of this Bill is sensitive and, therefore, likely to provoke strong views either in support of or in opposition to the principle of the introduction of a deemed consent system for organ donation in Wales.

97. The majority of the responses we received did not support the introduction of such a system. However, the results of the various public attitude surveys conducted over recent years have shown support for a change to an opt-out system. We believe that it is difficult to be definitive about the state of public opinion on this particular Bill.

98. Given the importance of public awareness of any change to the law, we believe the Minister must make every reasonable effort to ensure that people understand the new system and the options available to them under it.

The principle of deemed consent

99. All members of the Committee support the principle of increasing the number of organs available for transplantation. We agree with witnesses and the Minister that organ donation has the ability both to save and transform lives.

100. The majority of us were content with the principle of deemed consent, and its introduction in Wales via the Bill.

101. Two members of the Committee, Darren Millar AM and William Graham AM, did not support the introduction of a system of deemed consent for organ donation in Wales.

102. Regardless of our views on the principle of an opt-out system, we have a number of concerns about specific issues arising from the Bill.

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[66] RoP, paragraph 278, 24 January 2013, Health and Social Care Committee

These are listed below and discussed in more detail in the subsequent chapters of this report:

- infrastructure and capacity;
- the potential for unintended consequences as a result of implementing the Bill;
- the role of the family;
- arrangements for appointed representatives;
- residency requirements;
- the re-development of the registration system;
- arrangements for the communication and education campaign to accompany the Bill;
- the level of public awareness necessary in order for consent to donation to be deemed;
- training requirements;
- the financial implications of the Bill;
- novel forms of transplantation;
- the principle of deemed consent in relation to donation after circulatory death (DCD);
- the code of practice to accompany the Bill;
- arrangements for evaluating the success of the Bill.

4. Increasing organ donation rates

Evidence base

Evidence from consultees

104. In December 2012, the Welsh Government published a research paper which examined international evidence on the impact of an opt-out organ donation system on organ donation rates. The report concluded that, although opt-out systems are associated with an increase in organ donation rates and an increase in a willingness to donate, it cannot be inferred that the increased organ donation rates are as a direct result of presumed consent.

105. Other factors such as education and awareness programmes, infrastructure improvements, greater health expenditure, increased mortality from donor-providing causes etc, may all have an impact on the donation rates.

106. Although the Explanatory Memorandum recognises that, as well as the organ donation system itself, a range of factors such as cultural and psychological considerations can affect donation rates, it states that changing to an opt-out system of organ donation in Wales is much more likely than not to result in an increase in donation and transplantation rates.

107. This was not the view of a number of stakeholders, including the UKDEC, who raised doubts about the evidence that deemed consent would lead to an increase in donations.

108. On this point, the UKDEC said:

> "A key assumption is that the switch to deemed consent will lead to an increase in donations. Whilst UKDEC recognises the political imperative for introducing deemed consent in Wales, there are doubts about the evidence. Overall systems in different countries vary, and it is not necessarily possible to compare one opt-out system with another. The evidence linking opt-out systems with increased donation is equivocal or at best weakly in favour of opt out having an effect. In order for confidence in the system to be upheld, those tasked with

> implementing it will need to be convinced that the time and resources involved could not be better deployed elsewhere."[67]

109. This was echoed by Professor Saunders who stated that he was unsure why there was such a determination to press ahead with the legislation given that the inquiries of the UK ODTF and the previous Health, Wellbeing and Local Government Committee examined the international evidence and subsequently concluded they were against introducing legislation.[68]

110. In contrast, the Kidney Wales Foundation stated that it was "vital" there was a change in the law, and although communication and education were important, they alone did not increase the organ donation rate.[69]

111. The British Heart Foundation Cymru stated:

> "International data shows that an opt-out system is associated with higher donation rates and several studies suggest that it would increase the numbers of organs available for transplantation by up to 30% in the UK. This means that Wales could possibly project an increase of between 14 and 54 donors over a 3-5 year period after the introduction of opt-out legislation."[70]

112. However, a number of witnesses raised issues about the international evidence on this matter, and questioned whether increases in rates of donation were a direct result of the introduction of presumed consent legislation.

113. On this point, the Bench of Bishops of the Church in Wales said:

> "It is arguable that countries which have such a scheme as is proposed (e.g. Spain) have seen an increase in donors only when transplantation services have been vastly improved."[71]

114. Christian Action Research and Education highlighted that:

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[67] Written evidence, HT(Org)4

[68] RoP, paragraphs 305-306, 24 January 2013, Health and Social Care Committee

[69] RoP, paragraph 467, 24 January 2013, Health and Social Care Committee

[70] Written evidence, HT(Org)21

[71] Written evidence, HT(Org)1

> "(…) the Welsh Government's own international comparison shows that Wales' current organ donation rate 24.9 is better than that of most presumed consent countries (16) and similar to that of two. Moreover, one country that is outperforming Wales does not operate on the basis of presumed consent. This clearly demonstrates that presumed consent legislation is not even a key consideration to increasing organ availability."[72]

115. Professor John Fabre said that the Explanatory Memorandum contained a:

> "(…) factual error in [paragraph] 102 in the section entitled "Evidence Base to Establish Impact of Proposed Legislation". It states "For example, an opt-out system is operated in Spain and it has the highest donation rate in the world with approximately 32 deceased donors per million of population". Spain does not operate a presumed consent system."[73]

116. He quoted from an article he had co-authored, published in the British Medical Journal[74], that said:

> "Crucially, Spain does not have an opt-out register for those who do not wish to become organ donors. Not a penny is spent on recording objections to organ donation by Spanish citizens, nor on public awareness of the 1979 legislation. Clearly, the presumed consent law in Spain is dormant, and it pre-dates key policy changes made in 1989. In these circumstances, Spain's outstanding deceased organ donor rate cannot reasonably be attributed to its presumed consent laws".[75]

Evidence from the Minister

117. The Minister told us that, looking at the international evidence, "countries that have a soft opt-out system consistently outperform countries that do not have that legislation."[76]

118. The Minister's policy official expanded on that point, saying:

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[72] Written evidence, HT(Org)23
[73] Written evidence, HT(Org)80
[74] Ibid.
[75] Ibid.
[76] RoP, paragraph 171, 20 February 2013, Health and Social Care Committee

> "The Abadie and Gay paper did an analysis that allowed for many different societal factors in (…) countries [with consent legislation] for example, whether it was due to economic wealth, health systems, or religious views.. (…)It said that, allowing for those differences, you could still produce evidence that the countries with presumed consent systems are associated with higher rates of organ donation."[77]

119. He went on:

> "(…) in one of the evidence papers that we produced around Christmas time, there is a graph that shows the donation rates for different countries in terms of informed consent against presumed consent. If you looked at the top half of the graph, you would see around 20 countries there, 17 of which have presumed consent. (…) That supports our argument that those countries that have presumed consent are associated with higher rates of donation. That is mainly due to families having greater clarity regarding individuals' wishes, which is brought about by the debate that the change in the law encourages."[78]

120. The Minister said she had reviewed the international evidence at the end of last year, and believed "that it is time for a change and that this is the right way forward."[79]

121. However, she acknowledged that the Bill alone would not "give us all the donors that we would like". She went on:

> "It is a matter of having lots of different strings to the bow, to pull together."[80]

122. Further to this, her policy official told us:

> "(…) the evidence paper that we published alongside the Bill in December says that it is communication and legislation working together and that the greatest success in increasing

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[77] RoP, paragraph 182, 20 February 2013, Health and Social Care Committee

[78] Ibid.

[79] RoP, paragraph 101, 20 February 2013, Health and Social Care Committee

[80] RoP, paragraph 298, 24 January 2013, Health and Social Care Committee

> donation rates has been in those countries that have legislative back-up for opt-out systems."[81]

123. Responding to the points raised by Professor Fabre about inaccuracies in the Explanatory Memorandum, the Minister stated:

> "I have been provided with an overview of the robust international research (…) developed by our Social Research official. (…) It re-iterates the conclusion of the research we published in December, that is opt-out laws are associated with increased organ donation rates and increased willingness to donate (…) We stand by the text of the Explanatory Memorandum".[82]

124. She went on:

> "I would add we are not seeking to emulate the law or practice of any particular nation. (…) We are developing an organ donation system which is right for Wales, taking full account of international law, practice and evidence of outcomes."[83]

Our view

125. In relation to the international evidence, we note that the Welsh Government's research paper on this subject concluded that it could not be inferred that increased organ donation rates in countries with a system of presumed consent were as a direct result of presumed consent.

126. We also note the work of the Health, Wellbeing and Local Government Committee in the third Assembly on international models of presumed consent.[84]

127. Further to this, we recognise that a range of factors, including education and awareness programmes and infrastructure improvements, can all influence donation rates.

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[81] RoP, paragraph 299, 24 January 2013, Health and Social Care Committee

[82] Letter from the Minister for Health and Social Services, 7 February 2013

[83] Ibid.

[84] National Assembly for Wales, Health, Well-being and Local Government Committee, Inquiry into presumed consent for organ donation, July 2008

128. On the basis of international evidence, we believe that, by itself, a change in the law of the sort proposed in the Bill is unlikely to be decisive in driving up the rate of organ donation in Wales.

129. However, international evidence has also demonstrated that a package of measures, with an opt-out system of consent as a component part of that, has been successful in increasing the number of organ donations in other countries. We acknowledge that the Minister has said that this Bill will be one of a number of such measures.

Infrastructure and capacity

Evidence from consultees

130. A number of respondents questioned whether the infrastructure was in place within Wales to support an increase in organ donation rates.

131. The Kidney Wales Foundation told us:

> "Kidney Wales believes the Welsh Government should consider infrastructure/systems across the world particularly in Europe. For example, Spain, who has the highest donation rates in Europe, has approximately three times as many intensive care beds per million populations as the UK. France who also demonstrates good donation rates of 25.3 pmp have 9.3 Intensive Care beds per 100,000 population (vs. 3.2 in Wales)." Wales" donation rate (2009/10) of 13.7 per million population equated to 41 deceased donations."[85]

132. They expressed particular concerns about critical care bed capacity.

> "A limited Critical Care bed stock influences admission policies to intensive care units, and also end-of-life care policies, both of which can potentially influence organ donation rates… We agree with Critical Care Network in Wales that a successful increase in organ donation will be reliant on adequate resources and capacity to care for and manage potential donors… It is therefore recommended that there is an increase

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[85] Written evidence, HT(Org)25

> in provision of Critical Care beds across the country to bring Wales in line with European neighbours."[86]

133. With regard to critical care capacity, Dr Peter Matthews from the Academy of Royal Colleges Wales (ARCW) stated that he also had concerns about capacity:

> "(…) and whether that is sufficient to sustain any increase in organ donation. We have concerns about whether the opt-out system might compromise the integrity of critical care specialists when dealing with end-of-life issues (…)"[87]

134. He went on to say:

> "I know that many of the proposals state that presumed consent has been a major factor in increasing organ donation across Europe, but Wales now has the second highest donation rate across Europe in terms of countries without a presumed consent—or 'deemed consent', to be more correct—system in place. However, it appears that all of the other countries have a greater capacity for beds. If you want to look at organ donation rates in a different way, the UK has the highest number of organ donors per critical care bed in the world. So, we are running a very tight system already. We have turned down patients who might potentially have been organ donors, because we do not have the capacity—certainly in Swansea, we are running at about 110% to 120%—and even if we had a marginal increase in numbers it would have a dramatic knock-on effect on the amount of elective surgery that we could get through as well, which is always being cancelled on a weekly basis."[88]

135. A number of other respondents made a similar point about capacity and infrastructure, including Professor Saunders, Mr Phil Walton (SNOD) and Professor Ceri Phillips.

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[86] Written evidence, HT(Org)25
[87] RoP, paragraph 56, 30 January 2013, Health and Social Care Committee
[88] RoP, paragraph 101, 30 January 2013, Health and Social Care Committee

136. British Heart Foundation Cymru told us that the Minister should provide further detail on the infrastructure in place to ensure a successful transition to the opt-out system. They went on:

> "This should include investment in on-going training in implementing and operating in a soft opt-out system for health care professionals particularly for transplant co-ordinators and staff working in intensive care and emergency departments… The Welsh Government should also ensure that the right financial incentives are in place for a successful move to opt-out. Increasing intensive care beds should be a priority of the Welsh Government before this legislation is implemented."[89]

137. The RCN said they wished to "strongly emphasise that introduction of any new system or approach to organ donation requires corresponding investment in public education and expansion of infrastructure. Identifying larger numbers of willing donors is only valuable if the supporting infrastructure is able to cope with the additional workload."[90]

Evidence from the Minister

138. Responding to concerns expressed by witnesses about insufficient critical care capacity in Wales, the Minister told us:

> "If this legislation is passed, we expect to increase the number of donors by around 25%, which equates to about 15 per year. On average, it is three organ or tissue donations per donor and that would be 45 in a year. Obviously, retrieval will take place in Wales, but the majority of operations will take place in England."[91]

139. She went on:

> "I accept that there is more work to be done, but I am assured that we can cope with the extra work. The funding is up to the local health boards. However, you have to remember that it will probably be one per health board per five months; it is not a

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[89] Written evidence, HT(Org)21
[90] Written evidence, HT(Org)15
[91] RoP, paragraph 53, 20 February 2013, Health and Social Care Committee

> huge amount and health boards have assured me that they will be able to cope with that."[92]

140. In subsequent correspondence, the Minister told us that she had received a report from the Critical Care Network and "it is currently being considered." She said she would share any information with us as soon as possible.[93]

Our view

141. We believe that matters of infrastructure and capacity will be critical to the success of this policy; this is supported by international evidence.

142. We were, therefore, concerned to hear that, despite currently having the second highest organ donation rate in Europe for countries with a deemed/presumed consent system, Wales has one of the lowest levels of critical care capacity. However, we recognise that, on this matter, it is not possible to make simple comparisons with other countries, as each has its own arrangements for deploying resources in relation to critical care.

143. Nevertheless, we believe that an increase in the rate of organ donation, even at the modest level envisaged as a result of the Bill will have consequences for critical care capacity. Based on the evidence we have received, we are yet to be convinced that such capacity exists to support the current system. Any future increase in organ donor numbers, as envisaged by the Minister, would exacerbate current issues in relation to capacity.

144. We note that the Minister had commissioned and received a report from the Critical Care Network on critical care capacity in Wales, and that this has been prepared in the context of current consultation and proposals for reconfiguration of NHS services in Wales.

145. We recommend that, before the end of Stage 2 proceedings, the Minister prepare and publish a detailed plan for the future of critical care capacity in Wales, including resource implications, the timescales for any developments in this area, and how these matters will relate to the Bill.

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[92] RoP, paragraph 53, 20 February 2013, Health and Social Care Committee

[93] Letter from the Minister for Health and Social Services, 28 February 2013

146. Finally, in the event that the Bill results in a greater than anticipated increase in organ donor numbers, we recommend the Minister prepare a contingency plan in order to be able to respond to this.

Impact of the UK Organ Donation Taskforce

Evidence from consultees

147. The UK ODTF was established in December 2006 to identify barriers to organ donation and to recommend what action should be taken to increase the number of organ donations. The Taskforce made 14 recommendations in their first report, 'Organs for Transplants', published in January 2008. It was believed that the recommendations, if implemented together, would lead to a 50 per cent increase in organ donation in the UK within five years. This would lead to an additional 1,200 transplants a year resulting in an annual total of around 4,200 solid organ transplants.[94]

148. The second report of the ODTF, 'The potential impact of an opt-out system for organ donation in the UK', published in November 2008, concluded that the more the Taskforce examined the evidence for presumed consent the more multifaceted and multidimensional the issue of increasing donor numbers became. The Taskforce recommended that an opt-out system should not be introduced in the UK at that time.

149. We were told that, as a result of the Taskforce recommendations, organ donation policy is being implemented across the health boards. Consequently, strong links with counterparts are being formed, there is an increase in awareness through education, and consent rates have increased as a result.

150. Cardiff and Vale University Health Board Organ Donation Committee said:

> "The Bill will not be a substitute for the Organ Donation Taskforce Recommendations made in 2008. For the Bill to be successful it is essential to adhere to the Taskforce Recommendations and the guidelines developed by NICE, in

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[94] Organ Donation Taskforce (ODTF)

> particular those in relation to referral of all potential donors and collaborative requesting."[95]

151. Mr Phil Walton explained how the work of the Taskforce sat alongside other measures:

> "(…) in the last four and a half years, or since the taskforce recommendations were released, we have seen a considerable increase in organ donation in south Wales in the patch that we are responsible for. There has been a 42% increase. That is due to the organ donation taskforce recommendation implementation and the NICE guidelines in collaboration with the clinical leads on organ donation, the specialist nurses on organ donation and the chairs of the donation committees in those hospitals."

152. He went on:

> "I think that it has come at a time when we are approaching the end of our five-year target from the organ donation taskforce. The NHSBT is about to publish its new strategy to take us up to 2020 and this goes hand-in-hand with that."[96]

153. We received a number of suggestions from respondents about other measures that could be taken to increase donation rates, rather than legislating for a soft opt-out system. These suggestions included:

- mandated choice; requiring every individual to make and record a decision about organ donation;
- including an option to sign up to the ODR on GP or dentist registration forms, passport applications, voter registration forms or council tax registration forms;
- encouraging GPs to discuss routinely the issue of organ donation with their patients;
- increasing the number of donation coordinators.

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[95] Written evidence, HT(Org)12

[96] RoP, paragraph 277, 20 February 2013, Health and Social Care Committee

Our view

154. We note that, since the release of the ODTF recommendations in 2008, there has been a considerable increase in the number of organs for donation in Wales. We also note that NHSBT will shortly be publishing a new strategy to run to 2020. It is not clear to us that all the benefits of the Taskforce's recommendations have yet been realised.

155. Having heard the evidence, however, we believe that much more could be done in terms of public awareness raising, encouraging people to register on the ODR and making improvements to the efficiency of the current system.

156. We do not consider the Bill to be a substitute for these matters. Rather, given that the timeframe for implementation of the Bill is two years, we believe that continuing work can and should be undertaken on these matters. If this were the case, we consider the Bill has the potential to make significant progress in terms of increasing the number of organ donors.

157. It should be noted, however, that some members of the Committee feel the introduction of the Bill at this time is premature, given that existing measures to increase donation rates have not yet been fully implemented and new ways of increasing donation could be explored.

Missed cases

Evidence from consultees

158. In his evidence, Mr Phil Walton stated that there are currently 15 SNODs across Wales and that the funding for this was based on the potential for organ donation in the region.[97]

159. He said that, based on key performance indicators, they knew that some potential donors were not identified, 'a missed case'. He said this was due to a number of reasons:

> "(…) there might be a case every couple of months where a patient could have been brain stem tested and was not

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[97] RoP, paragraph 218, 20 February 2013, Health and Social Care Committee

> referred, or where a patient was brain stem tested and was not referred. There are cases where patients have had treatment withdrawn and have not been referred. We would see that about once a month, at least [in the south Wales region]."[98]

160. Mr Phil Walton also referred to an increase in consent rates to donation when a SNOD was part of the discussions with families:

> "The SNOD consent rate is classed as the SNOD-collaborative-approach rate, which means that if a SNOD is present in a room with a clinician, the success rate is around 70% to 75%. If it is a consultant-only approach it is around 50%."[99]

161. However, he said that specialist nurses were not always involved in the approaches to potential donors and their families, sometimes for "logistical reasons".[100]

162. This point was also made by NHSBT, who said:

> "(…) not every family is approached and supported by a specialist nurse for a whole range of reasons. In about a third of cases, it may be the intensive care doctor who has been looking after the family, or someone else, who will be asking them about organ donation."[101]

163. Mr Phil Walton confirmed that, taken together, both of the matters set out above could potentially result in three or four missed cases per year in south Wales alone.[102]

164. Linked to the matter of missed opportunities for organ donation, the RCN said:

> "(…) the RCN strongly encourages the Welsh Government to make explicit the principle that organ and tissue donation should be integrated into the culture of best practice in end-of-

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[98] RoP, paragraph 251, 20 February 2013, Health and Social Care Committee
[99] RoP, paragraph 262, 20 February 2013, Health and Social Care Committee
[100] RoP, paragraph 247, 20 February 2013, Health and Social Care Committee
[101] RoP, paragraph 592, 24 January 2013, Health and Social Care Committee
[102] RoP, paragraphs 267-268, 20 February 2013, Health and Social Care Committee

> life care. The RCN believes that this will have a substantially beneficial impact on donation rates."[103]

Evidence from the Minister

165. In relation to the evidence from Mr Phil Walton about missed cases, the Minister told us that it was not necessarily the case that once a potential donor had been identified, donation would always follow:

> "Last year there were 250 potential donors in Wales, resulting in 67 actual donors. Taking potential donors through to the point of becoming actual donors involves a complex set of decisions and actions, including identification and referral of the patient; neurological death testing in DBD cases; approach to families and final consent to donation. There is a fall-off rate at each of these stages, thereby reducing the number of donors going forward. (…) We have always said an opt-out system is part of a wider series of actions to address these range of factors and we are working with NHSBT on a new UK strategy which will seek to further address some of these issues."[104]

166. She said there had been improvements in referral rates over recent years and acknowledged that better identification and referral of patients could see an increase in the number of families approached.[105]

167. She went on:

> "However, the single largest significant change will come from improving the consent rate from the current 65 per cent. Our continued view is until we tackle the issues around the consent rate, we are unlikely to see further significant gains. Opt-out systems help to clarify wishes and give relatives greater reassurance the wishes of their loved ones are being followed."[106]

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[103] Written evidence, HT(Org)15
[104] Letter from the Minister for Health and Social Services, 28 February 2013
[105] Ibid.
[106] Ibid.

Our view

168. We acknowledge that, for a number of reasons, not all potential donors go on to become actual donors.

169. However, as we heard in evidence, there are a number of potential donors who are not being identified under the current system; ‘missed cases’.

170. We also heard that consent rates are improved in cases where both a SNOD and clinician are present for discussions with families about donation (SNOD-collaborative approach), but that because of logistical reasons, this could not always be the case.

171. We believe that, if more of these missed cases were identified and if a greater number of cases involved a SNOD-collaborative approach, this could have the effect of significantly increasing donor numbers in any event. That said, we acknowledge that, ultimately, some families would not wish for donation to proceed.

172. We wish to draw this to the Minister’s attention as part of his work with NHSBT on a UK strategy to address this issue amongst others.

Unintended consequences

Evidence from consultees

173. A number of respondents highlighted the importance of public confidence in the system and the impact that any damage to that confidence may have on donations rates.

174. On this first point, Professor John Saunders said:

> “The problems with the Bill are the hazards it creates for damaging the present programme of transplantation. That damage will be contingent on certain practicalities and how they are handled. A single mishandled opportunity in the hands of a critical media could create havoc with donation numbers; a vociferous opposition could prime the public in a negative

> manner if practical issues are not addressed. Among these are the way the modified Register is operated."[107]

175. The UKDEC told us:

> "(…) we have concerns about the practicalities of it and, indeed, sometimes from an ethical point of view, the effect that it may have on other people, albeit unintended. For example, if, by doing this, the confidence in the whole process of organ donation diminishes elsewhere, then of course the actual adverse effect is greater than the benefit (…)".[108]

176. NHSBT also highlighted the importance of public confidence in the system:

> "The new UK wide register which will be developed as a consequence of this bill needs to retain the confidence of the general public as well as the medical community. Care will have to be taken while developing the new register to ensure it retains its existing role as a register of people's wishes and at the same time develops a new legal role as a register of people who have opted-out."[109]

177. In addition to Professor Saunders, a number of other respondents, including Patient Concern, highlighted the dangers of adverse publicity on public confidence in the system.

178. On this point, the British Transplantation Society (BTS) said:

> "Adverse publicity is the major concern of the BTS. If a family were not present at death, but subsequently come forward to say that the deceased did not agree to donation, and that his wishes had been overlooked or that the database recording his wishes (the ODR) was inaccurate (which has happened with the ODR), there would be significant adverse publicity which would damage transplantation not only in Wales, but also the rest of the United Kingdom. The BTS would be reassured to know that

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[107] Written evidence, HT(Org)28

[108] RoP, paragraph 255, 30 January 2013, Health and Social Care Committee

[109] Written evidence, HT(Org)5

> contingencies for such an eventuality have been considered and will be in place ahead of such an event."[110]

179. Linked to the issues of public confidence and adverse publicity, we have heard from a number of respondents about their intention to opt out of any new system. While many objected to the principle of deemed consent, for others, not having trust in the system (including a perception of the state 'taking organs') was another factor.

Our view

180. For reasons already identified, we have continuing concerns that, in an unintended way, the Bill could have the effect of reducing organ donation rates.

181. We believe the Minister must demonstrate that he is alert to these possible unintended consequences and that adequate preparations have been made to deal with them.

Duties of Welsh Ministers in the Bill

Evidence from consultees

182. A number of witnesses, including the WKPA, told us that they supported the inclusion in the Bill of a duty on Welsh Ministers to promote and raise the awareness of transplantation.

183. On this point, the BTS said:

> "We very much welcome section 2 of the Bill, where the Welsh Ministers have a mandate to promote transplantation."[111]

184. Similarly, the Kidney Wales Foundation said:

> "We support the "duty" placed on Welsh Ministers in Section 2 to promote transplantation. It is often the case that Westminster has not done so as well as Wales and Scotland which is borne out in the numbers of the population on the Organ Donation Register. In recent times First Ministers, Health Ministers and Cabinet Members together with leading

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[110] Written evidence, HT(Org)7

[111] RoP, paragraph 171, 30 January 2013, Health and Social Care Committee

> politicians across Wales have taken this duty seriously. We are pleased to see it enshrined in the law."[112]

Evidence from the Minister

185. In relation to the duty in section 2 of the Bill for Welsh Ministers to promote transplantation, the Minister told us:

> "One main safeguard is our commitment to ensuring that everyone in Wales becomes aware of the new legislation and how it works. (…) We are … committing ourselves to continuing awareness raising into the future through a duty in the Bill to promote transplantation."[113]

186. She said that the duty on Welsh Ministers under the Bill would be to "continue to promote and publicise this, even after the law is enacted."[114]

Our view

187. We note the evidence from respondents in support of the duty on the face of the Bill for Welsh Ministers to promote transplantation.

188. We consider this to be an important part of the overall policy intention to increase the number of organs for donation in Wales.

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[112] Written evidence, HT(Org)25

[113] RoP, paragraph 278, 24 January 2013, Health and Social Care Committee

[114] RoP, paragraph 293, 24 January 2013, Health and Social Care Committee

5. Authorisation of transplantation activities

Consent and the role of the family – a 'veto' or providing information in relation to donation

Background

189. Section 3 of the Bill introduces the concept of 'deemed consent'. The section also sets out the transplantation activities to which the consent applies.[115]

190. The Bill provides families with the right to provide information regarding the wishes of the deceased and whether they would, or would not, have agreed to their consent being deemed.[116]

191. Section 5 of the Bill makes provision for excepted adults. The Mental Capacity Act 2005 states that a person must be assumed to have capacity to make decisions unless it is established otherwise.[117] On this matter, the Bill replicates the provisions of the Human Tissue Act 2004 "so as to require either the express consent of the individual, or the express consent of a qualifying relative or the express consent of an appointed representative."[118]

192. Section 17(2) makes provision for 'qualifying relationships'. In relation to this, the Explanatory Memorandum states:

> "(…) it is considered that any person in this list [of qualifying relationships] should be able to provide information. The only time that relationships are ranked is when express consent is to be given on behalf of a child or an excepted adult."[119]

Evidence from consultees

193. All respondents agreed that seeking the views of the family in relation to consent to donation was very important. However, there were differing views on the question of whether the family of the deceased should provide information in relation to the decision about

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[115] EM, page 75, paragraph 11
[116] EM, page 18, paragraph 42
[117] EM, page 17, paragraph 36
[118] EM, page 77, paragraph 25
[119] EM, page 20, paragraph 44

donation or whether they should have a ‘veto’, and whether the Bill should be clearer about this.

194. Dr Clamp from the HTA explained that, under the Human Tissue Act 2004, there is no right of veto for the family, but that, in practice, families’ views are sought.[120]

195. He went on:

> “The fact that the family will still be involved in the process under the Welsh Government’s proposals means that this key safeguard remains in place. Although the family will not have the right to veto the donation if a recorded yes is in place or consent is deemed, if they are able to provide evidence that would satisfy a reasonable person that the deceased did not wish to be a donor this will be accepted.”[121]

196. Dr Lewens from the Nuffield Council on Bioethics made the same point about families being consulted in practice under the current arrangements and went on to say:

> “As I understand it, [seeking the views of families] will continue to be the case under the proposed system. There are two good reasons for taking family wishes into account. First, family members may be well placed to know of recent events that inform the team about the wishes of the individual. So, there, the involvement of the family need not override your own views, but it rather helps the team to understand what your views are. That will still be the case—and I think it is an important part of the case—under the revised proposals.”[122]

197. He continued:

> “It is also just a fact that transplant teams are understandably very unwilling to cause family members undue distress at what is already a very difficult time for them by going against their wishes. (...) it is one thing to say that the family should have an input into explaining what the donor’s wishes may have been, but it is another thing to say that it is important not to bring

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[120] RoP, paragraph 175, 30 January 2013, Health and Social Care Committee
[121] Written evidence, HT(Org)27
[122] RoP, paragraph 267, 30 January 2013, Health and Social Care Committee

> about undue distress to family members; to translate that into a claim that any family member has a right of veto, with a long list, may well involve adverse consequences and counter-productive consequences in terms of the overall ability of the proposed legislation to increase rates."[123]

198. Professor Harpwood, Chair of the Organ Donation Committee, Cwm Taf Health Board, told us

> "(…) it would be dangerous, perhaps, to state upfront that if any member of the family disagrees, there is not going to be a donation. That, in itself, would immediately start to ring alarm bells."[124]

199. Similarly, the Clinical Ethics Committee, Abertawe Bro Morgannwg University Health Board said:

> "The EM puts in various forms of words the intention to give real weight to the family's view and rightly makes clear that in the present system, as in that which would be created by the Bill, the family wield no formal veto. But there is real concern (…) about this part of what is proposed. (…) if in reality family members are still given a practical veto, then this Bill will achieve very little."[125]

200. The Bishop's Adviser, Church in Wales, told us:

> "(…) we would not want to go as far as to say that relatives should have a veto if the deceased person wanted to donate (…)."[126]

201. Sally Johnson from NHSBT told us that they were in the process of developing a new strategy for organ donation for the UK, which they hoped to publish later this year, and that in relation to the system proposed under the Bill:

> "When we approach a family in a situation of deemed consent, I would expect that we would also be saying that the assumption

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[123] RoP, paragraph 268, 30 January 2013, Health and Social Care Committee
[124] RoP, paragraph 65, 30 January 2013, Health and Social Care Committee
[125] Written evidence, HT(Org) 26
[126] RoP, paragraph 167, 7 February 2013, Health and Social Care Committee

> is that the person wanted to be an organ donor and, therefore, we would be seeking the family's support, rather than approaching it in a more neutral way, as we currently do, and, where there is an opt out, we will not be talking to them about it at all (…)."[127]

202. Mr Phil Walton (SNOD), told us that on the whole families did not regret their decisions to agree to organ donation. He said:

> "The evidence that is out there suggests that families regret not donating when they have had time to think on it. It is understandable why families say 'no', because they are being asked to make a decision on the worst day of their lives."[128]

203. We also heard evidence of cases where patients on the ODR do not have any family or nominated representatives. On this point, Dr Dariusz Tetla, told us:

> "If the patient is on the organ donor register and we cannot find the family and they do not have nominated representatives, the current opt-in system allows us, in some situations, to take their organs with some reservations—that the organs will be used in 48 hours and, if they are not used, they will be destroyed after 48 hours. My concern about the new opt-out system is whether deemed consent will be sufficient to carry out such an activity without the family being available with the same kind of patient. If not, the numbers of this type of donor will decrease (…)."[129]

Clarifying the role of the family in the legislation

204. A number of stakeholders told us that the role of the family should be clearer on the face of the Bill, whereas others felt that to do this might be unnecessarily restrictive.

205. On this point, Patient Concern told us:

> "It would certainly be a lot better if it [a family veto] was on the face of the Bill. If it said that if your relatives said 'no', that

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[127] RoP, paragraph 591, 24 January 2013, Health and Social Care Committee
[128] RoP, paragraph 298, 20 February 2013, Health and Social Care Committee
[129] RoP, paragraph 76, 30 January 2013, Health and Social Care Committee

> would be 'no', that would ease my mind considerably. It is not what the Bill says."[130]

206. The representative of the Muslim Council of Wales made a similar point:

> "If it is specifically mentioned [in the Bill] that family consent will be taken, that would soften it (…)."[131]

207. The Bishops' Adviser, Church in Wales, told us:

> "(…) It possibly would be better if the role of the family was more clearly spelled out in the actual Bill, rather than in the guidance. The guidance can be changed at any point, and if it was in the Bill there would be something there. This is a bit of a personal view because it is not something that has been widely discussed. I am not sure that the use of the term 'family veto' is helpful either. If a person has made a decision, I think that that decision should stand. If it was written into the legislation rather than the guidance, that would probably be helpful."[132]

208. The Association for Palliative Medicine of Great Britain and Ireland said:

> "The family's role is not clear enough. There are some ambiguities in the account of what influence they have over decisions and whether this role amounts to exercising a veto over retrieval. Resolving these would help to clarify their role. Families' experience of decisions around the end of life is pivotal in influencing their bereavement reactions and is a significant public health problem as well as one with specific and direct effects on public confidence in organ transplantation."[133]

209. The Bench of Bishops of the Church in Wales highlighted some differences in the Welsh Government's position on the question of a family veto:

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[130] RoP, paragraph 22, 7 February 2013, Health and Social Care Committee
[131] RoP, paragraph 198, 7 February 2013, Health and Social Care Committee
[132] RoP, paragraph 192, 7 February 2013, Health and Social Care Committee
[133] Written evidence, HT(Org)17

> "The Welsh Government believes that by allowing "someone in a qualifying relationship to the deceased immediately before death to provide information that would lead a reasonable person to conclude that the deceased would not have consented" is allowing relatives a say and is a soft out option. That is at variance with its previous statements regarding a soft out option where relatives could veto transplantation where someone had not opted out. This could potentially lead to very difficult encounters between relatives and medical staff."[134]

210. Although Professor Saunders said he was not opposed to the role of the family being clearer on the face of the Bill, he did warn that "if you water it down too much, the danger is that you will lose any potential advantages in the legislation. (...) The closer you are to ordinary practice, the less benefit there is in passing the legislation".[135]

Qualifying relationships - ranking

211. On the matter of qualifying relationships under the Bill, some stakeholders told us they favoured a hierarchical or ranked list, whereas others suggested that a ranked list was "not without its problems."[136]

212. The HTA told us that there was a hierarchy provided for in the Human Tissue Act 2004, and the absence of such a hierarchy in the Bill "had the potential to create more confusion and more difficulty."[137]

213. This was supported by Dr Matthews from the ARCW, who believed that the qualifying relationships should be ranked to provide clear guidance for what happens if a family disagrees and to avoid confusion for clinicians.[138]

214. The Clinical Ethics Committee, Abertawe Bro Morgannwg University Health Board, were also in favour of a hierarchy for the purposes of clarity:

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[134] Written evidence, HT(Org)1

[135] RoP, paragraph 277, 7 February 2013, Health and Social Care Committee

[136] RoP, paragraph 222, 20 February 2013, Health and Social Care Committee

[137] RoP, paragraph 175, 30 January 2013, Health and Social Care Committee

[138] RoP, paragraph 56, 30 January 2013, Health and Social Care Committee

> "(...) it is not clear what should be done in the likely event of disagreement between people with qualifying relationships. Such disagreements are common and there is often uncertainty about who knows best. (...) A formal hierarchy or ranking of kinds of qualifying relationship might make things clearer."[139]

215. They went on:

> "We note that the lack of ranking is intentional but nonetheless we think that having one would reduce clinicians' uncertainty. We see no argument for not ranking those relationships; the EM says that the intention is for anyone on the list to be able to provide the necessary information about the person's former wishes, but ranking them would not obstruct that intention. It would merely strengthen the guidance for clinicians and transplant teams in the likely event that those with qualifying relationships disagree about the person's former wishes."[140]

216. Patient Concern[141] and the BTS both favoured some form of hierarchy. The BTS said it believed a hierarchy would help "so that the specialist nurses or the intensive care unit doctors, who talk to the relatives, can identify the person to whom they need to be speaking who carries the opinion of the deceased."[142]

217. The Bishops' Adviser to the Bench of Bishops, Church in Wales said that her personal view was that "perhaps it would be helpful if the ranking was retained in the same way as it is in the Human Tissue Act."[143] She went on to say:

> "On a practical level, it would also be incredibly difficult, because if you have not been able to trace people further down that list, and then somebody pops up afterwards and says, 'Oh, I would have objected if I had been consulted, but I wasn't', how would you deal with a situation like that?"[144]

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[139] Written evidence, HT(Org)26
[140] Ibid.
[141] RoP, paragraph 107, 7 February 2013, Health and Social Care Committee
[142] RoP, paragraph 179, 30 January 2013, Health and Social Care Committee
[143] RoP, paragraph 200, 7 February 2013, Health and Social Care Committee
[144] RoP, paragraph 202, 7 February 2013, Health and Social Care Committee

218. However, the Nuffield Council on Bioethics told us that "potentially, all kinds of different people could have that kind of valuable information regarding the wishes of the person. That would tell against a ranking system."[145]

219. Professor Saunders said that he would weigh the different family relationships accordingly and "for example, if a remote family member is putting up the objection and the others are quite strongly in favour, then the latter group should certainly win out. Any objection from no matter how distant a family member should not negate the donation."[146]

220. Both NHSBT and Mr Phil Walton referred to current practice in their evidence.

221. NHSBT told us:

> "In practical terms at the moment it can be helpful if they are ranked, but in practically every circumstance the specialist nurses are seeking to achieve agreement from everyone around the bedside about the best outcome for their relative, friend or whatever relationship that they have."[147]

222. Mr Phil Walton said that "the hierarchy of relationships in the Human Tissue Act 2004 is not without its problems. It is legislation that exists in practice at the moment and requires us to negotiate the matter on any given day".[148]

223. He said that "the nuclear family, as we once knew it, does not really exist in today's society" and that there would be cases where a friend of long standing had more information about the wishes of the deceased than a family member who had been estranged for a number of years.[149]

224. He went on:

> "Each category would have its own set of problems. In dealing with disagreements, the practical side is that we would see and

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[145] RoP, paragraph 290, 30 January 2013, Health and Social Care Committee

[146] RoP, paragraph 279, 7 February 2013, Health and Social Care Committee

[147] RoP, paragraph 584, 24 January 2013, Health and Social Care Committee

[148] RoP, paragraph 222, 20 February 2013, Health and Social Care Committee

[149] Ibid.

> get a feel for who is at the bedside (…) and work out who is closest to the patient. The next of kin is not necessarily the parent or brother; in some cases, they are appointed (…) We will get a feel for who is at the bedside and will bring the most important people, who are closest to the patient, into a room to have a discussion."[150]

225. He said that specialist nurses were comfortable with the guidance they had in this area and that "if it remains, there would not be any change in the way that we approach families. If it is to change, we would certainly work with the new system."[151]

Consent: Adults lacking capacity

226. A number of respondents raised concerns about judging capacity and how any disputes about capacity would be resolved, and what would constitute "a significant period" for the purpose of the Bill.

227. NHSBT and the UKDEC both said that the proposals for identifying adults lacking capacity did not seem very robust and that this placed additional responsibilities on SNODs.

228. Sir Peter Simpson from the UKDEC said:

> "(…) we do have concerns about the provisions in relation to adults lacking capacity. The Bill rightly recognises the need to protect people lacking the capacity to understand the notion of opting out. However the proposals for identifying such people do not seem very robust. The criterion of lacking capacity for a "significant period" before death is vague, and the reliance on discussion with families after death might lead to some very subjective assessments being made. Further work on how these decisions will be made in practice, and what support will be available for professionals and families, would be helpful."[152]

229. The Association for Palliative Medicine for Great Britain and Ireland told us that, in their view, "it needs to be made more clear how

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[150] RoP, paragraph 223, 20 February 2013, Health and Social Care Committee
[151] RoP, paragraph 222, 20 February 2013, Health and Social Care Committee
[152] Written evidence, HT(Org)4

and when the judgement of capacity should be made within the requirements of the Mental Capacity Act (2005)."[153]

230. On this matter, Dr Matthews from the ARCW told us that "issues of consent or capacity have to be decision-specific. So, just because someone has a mental illness, it does not necessarily mean that they will not have the capacity to understand issues about organ donation and either to opt in or to give their objections."[154]

231. On this point, Mr Phil Walton was able to give us some practical examples of two cases he had been involved in where the donor had a learning disability. He told us:

> "In one case, you had the family and the carers collaboratively making that decision [regarding donation], and, in the other, it was people from the care facility who were there, because there was no other family, but those people knew that patient extremely well."[155]

232. He said that, in both cases, "[the donors were] loving, caring individuals who probably would have supported organ donation, so the families were really very confident in making decisions on the behalf of those patients."[156]

233. In her evidence, Sally Johnson from NHSBT told us:

> "Nothing has changed in the Bill from the Human Tissue Act, but the defining difference it that opting out is very different from opting in or seeking to ask the family. Therefore, it is very important that people genuinely have the opportunity and the understanding to opt out. After much discussion with our colleagues and the officials in the Welsh Government, I think that we are accepting of the fact that we would take the family's word for the understanding of their relative."[157]

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[153] Written evidence, HT(Org)17

[154] RoP, paragraph 140, 30 January 2013, Health and Social Care Committee

[155] RoP, paragraph 302, 20 February 2013, Health and Social Care Committee

[156] RoP, paragraph 300, 20 February 2013, Health and Social Care Committee

[157] RoP, paragraph 560, 24 January 2013, Health and Social Care Committee

234. In relation to lacking capacity for a 'significant period before dying', Dr Peter Matthew from the ARCW said he thought that the Explanatory Memorandum was:

> "(…) a little bit wishy-washy. A 'significant period' of time with a 'reasonable person' does not really say much that you would be able to have as a substantive guideline to suggest what is a 'significant period' or whatever."[158]

235. However, he said that, in practice, this was not a "major issue, because families are usually fairly well aware of what is going on. If there were doubts about capacity, you would not go ahead in any case. So, I do not think that it is perhaps as big an issue as some people make it out to be. It may be an ethical or a legal concern, but, on a practical basis, it is not such a major issue." [159]

236. The BMA Cymru Wales told us that they considered the length of time that an individual had lacked capacity to be "irrelevant". In their view:

> "The relevant issue is whether they have had capacity for a reasonable period of time since the new system was implemented and therefore had the opportunity to opt out if they wished to do so. If it would be helpful to quantify this, rather than rely on subjective assessments of a 'reasonable period', it could be set at 6 months, in order to be consistent with the residency requirement and the period given to people approaching their 18th birthdays."[160]

237. In relation to disputes about capacity, Professor Harpwood told us that these were dealt with by the Court of Protection in the case of adults. She said:

> "Quite a substantial body of case law has been built up there now, and it is useful to refer to it. However, at the end of the day, it is the clinicians who have to make those decisions. I assume that any dispute would go to the Court of Protection. I

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[158] RoP. paragraph 140, 30 January 2013, Health and Social Care Committee

[159] Ibid.

[160] Written evidence, HT(Org)18

> am not sure quite how that would work. I do not know whether there would be problems for clinicians."[161]

Evidence from the Minister

Consent and the role of the family: a 'veto' or providing information in relation to donation

238. In the Explanatory Memorandum, in relation to the role of the family, the Minister stated:

> "As happens today, it is essential to involve next of kin in any situation where organ donation may be a possibility. This is because, for safety and quality reasons, it is very rare for donation to go ahead without their input."[162]

239. In oral evidence, the Minister clarified that:

> "(…) the Bill starts with the principle that we must clarify and uphold the wishes of the deceased (…) If a person becomes a potential donor, the family can provide evidence that the deceased wished to opt out."[163]

240. She went on to clarify that:

> "The situation is as it is now. There is no veto now. So, we are saying that the law is all about the deceased person's wishes and not the family's. However, if a family really objected, because, obviously, the clinicians have a duty of care to the family, the organ donation would not go ahead."[164]

241. We asked the Minister why she did not intend there to be a family veto under the Bill. She told us:

> "(…) it is because the law is about the deceased person's wishes and not those of the family. So, it is important that the law maintains that the choice to consent to the donation lies with

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[161] RoP, paragraph 138, 30 January 2013, Health and Social Care Committee
[162] EM, page 18, paragraph 41
[163] RoP, paragraph 279, 24 January 2013, Health and Social Care Committee
[164] RoP, paragraph 284, 24 January 2013, Health and Social Care Committee

> the individual when they are alive. That includes the choice to have their consent deemed."[165]

242. Further to this, the Minister's policy official told us:

> "(…) in the last survey that we did of the Welsh population, some 73% of people said that they wanted their wishes to be upheld. That strongly reinforces our belief that we should be looking through the lens of the individual's wishes and making sure that we go to all lengths to explore how they can be clarified with the family and how the family can be brought to understand their wishes."[166]

243. The Minister went on to confirm that, in a situation where a majority of family members expressed support for donation but one person objected, then donation would not take place.[167]

244. She told us she was:

> "(…) confident that every clinician in the country wishes to deal with families in an extremely sensitive manner and would not insist that organ donation goes ahead in the face of any strong opposition. This is the practical reality that applies now, even when people have opted in (…)".[168]

245. In clarifying the purpose of the discussions that would take place with the family, she stated that "it is not the case that an objection by someone in a qualifying relationship would be enough to prevent donation taking place" as consent has been deemed. The family are merely being asked if they have any information that the deceased would have objected.[169]

246. We asked the Minister to clarify whether, even in circumstances where a person had chosen to opt in to the register and any family member objected to donation taking place, that donation would not go ahead. She told us that was correct.[170]

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[165] RoP, paragraph 363, 24 January 2013, Health and Social Care Committee
[166] RoP, paragraph 366, 24 January 2013, Health and Social Care Committee
[167] RoP, paragraph 342, 24 January 2013, Health and Social Care Committee
[168] RoP, paragraph 279, 24 January 2013, Health and Social Care Committee
[169] Letter from the Minister for Health and Social Services, 14 February 2013
[170] RoP, paragraphs 421-422, 24 January 2013, Health and Social Care Committee

247. Adding to that, the Minister's policy official told us:

> "(…) you would have to look at it on a case-by-case basis, because there is no real rule or cut-off or anything like that. It is a question of exploring with them why they feel that they do not wish to proceed with the wishes of the deceased. Often, it is because they have concerns about the process and are worried about what is going to happen to their deceased relative. If those sorts of things can be worked through, the specialist nurse can very often effect a different outcome and people can agree on a way forward. If you have far-reaching objections from a family member, then it is unlikely to go ahead."[171]

248. The Minister also confirmed that:

> "(…) in practice people who cannot be identified or whose next of kin cannot be found will not be included in the deemed consent system."[172]

249. When asked about the difference between what is on the face of the Bill and what she has stated will happen in practice, the Minister stated that "it is important the law maintains that the choice to consent to donation is with the individual when they are alive including the choice to have their consent deemed".[173]

250. The Minister's legal adviser acknowledged there was "conflict in a number of areas in the Bill between what is on the face of the legislation and what will happen in practice, because of the reality that clinicians cannot be compelled to do something against their conscience."[174]

251. The Minister's legal adviser went on:

> "We have constantly tried to strike a balance on that—it exists in the current legislation, whereby, if somebody has opted in, the family is still involved in the discussion, and if the family feel strongly that donation should not proceed, then it does

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[171] RoP, paragraph 425, 24 January 2013, Health and Social Care Committee

[172] Letter from the Minister for Health and Social Services, 28 February 2013

[173] RoP, paragraph 363, 24 January 2013, Health and Social Care Committee

[174] RoP, paragraph 80, 20 February 2013, Health and Social Care Committee

> not. However, that is not what the legislation says. We have to be quite clear on the face of the legislation (…) as to what our system would be in Wales, and what we are saying is that you can opt in, opt out or do nothing. If you do nothing, your consent will be deemed if you fulfil the relevant criteria. That, in and of itself, in relation to human rights, would not be enough. There has to be a safeguard for relevant people—family and friends of long standing—to provide information, if they have it, that would lead a reasonable person to conclude that the deceased would not have consented. I think that it is very clear on the face of the legislation what it is proposed that the law will be in Wales."[175]

Qualifying relationships - ranking

252. On the matter of ranking the qualifying relationships in the Bill, the Minister told us there were, effectively, two lists of qualifying relationships in the Bill, each with the same people on them, but one related to deemed consent and the other to express consent:

> "The first unranked list exists for the purposes of deemed consent. Any person on the list at section 17(2) may provide information as to whether the deceased may have objected to their consent being deemed."[176]

253. She went on:

> "The reason this list is not ranked is because those people are not being asked to make a decision on donation, but rather to provide information. This is because the deceased has already made a decision to have their consent deemed and the law will recognise this as a valid consent, unless a person on that list can say otherwise. In practice, this does not mean every person on the list has to be contacted; clearly that would be unworkable. However, it provides the opportunity for those people present to say whether they know or think anyone else might know, if the deceased would have objected. (…) This is an important additional safeguard in relation to deemed

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[175] RoP, paragraph 80, 20 February 2013, Health and Social Care Committee

[176] Letter from the Minister for Health and Social Services, 14 February 2013

> consent: ranking the list would reduce the opportunity to say whether the deceased would have objected."[177]

254. She provided further clarification on this point in subsequent correspondence, saying:

> "The reasoning behind having an unranked list in deemed consent cases is very clear – it is in the interest of the deceased person because we cannot know who people may speak to about their views on organ donation. Therefore I considered it desirable to have a wider list rather than a narrower one. In light of ECHR considerations, a deemed consent system should allow adequate opportunity for information to be provided to show the deceased would not have consented. In practice, friends and family will be able to provide information if they have it."[178]

255. However, following discussions in Committee with regard to the ranking of qualifying relationships, the Minister agreed that she would give this matter further consideration.[179]

256. We asked the Minister about the role of the clinicians in interpreting these lists and whether this could cause difficulties for them. She said:

> "I believe there are sufficient safeguards in the existing clinical guidelines to protect the interests of clinicians for actions which they take in good faith and we can reinforce these in the Code of Practice."[180]

257. In relation to managing disagreements amongst family members, the Minister confirmed:

> "As happens now, disagreements (...) have to be carefully handled with emphasis being placed on open and sensitive discussions. The focus should be on the deceased person's wishes wherever possible, but healthcare professionals are not there to traumatise family members by insisting on donation.

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[177] Letter from the Minister for Health and Social Services, 14 February 2013
[178] Letter from the Minister for Health and Social Services, 28 February 2013
[179] RoP, paragraph 87, 20 February 2013, Health and Social Committee
[180] Letter from the Minister for Health and Social Services, 28 February 2013

> Each case has to be dealt with individually and in accordance with best practice which will be set out in the Code."[181]

Consent: Adults lacking capacity

258. In terms of including provisions in the Bill to protect individuals lacking capacity, the Minister said that a ranked list of qualifying relationships had been included for this purpose.

> "(…) For these deceased individuals, if they have not expressed a wish themselves, the decision on donation passes to the person at the top of the hierarchy of qualifying relationships."[182]

259. She went on:

> "The list is ranked because when a decision is called for, it would be impossible to give everyone on the list equal ranking as this would run the risk of no decision ever being taken. Therefore, in relation to express consent, we are not changing the current system and have retained the ranked relationships as provided for in the Human Tissue Act 2004."[183]

260. We asked the Minister how it could be ensured that a person's mental capacity would be judged correctly in practice. Responding to this, she said:

> "It will be the same as it is now. It is a very complex issue to establish whether a person has the necessary mental capacity to understand that their consent could be deemed; it is a very sensitive part of the process, and it will be woven into conversations with families at the time, when looking at other relevant medical information. If there is any doubt—if a family has any doubt that that person did not have the mental capacity—the donation would not go ahead."[184]

261. We also asked the Minister how the Bill would protect people with capacity issues where those issues were not known to family members or clinicians. The Minister's legal adviser told us:

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[181] Letter from the Minister for Health and Social Services, 14 February 2013

[182] Ibid.

[183] Ibid.

[184] RoP, paragraph 383, 24 January 2013, Health and Social Care Committee

> "It is more of a practical problem, and it must exist now. I acknowledge what you are saying: it is absolutely logical. They might not tell people. One would hope that if they have not told the family, it would be on the medical records. This would have to be explored with family members through discussion. It is obviously a case-by-case issue (…). Each case would need to be sensitively handled to ensure that those lacking capacity are protected."[185]

262. Further to this:

> "Some of the guidance that is already in existence, in terms of the Mental Capacity Act 2005 and so forth, talks about whether families have a reasonable belief as to whether their relative could understand something or make a decision about it. We would be looking at that kind of situation as well, as to what they would reasonably believe to be the case in relation to their relative."[186]

Our view

Consent and the role of the family

263. In relation to the giving of consent to donation, we note the Minister's evidence that the role of the family is an important safeguard in providing information about the wishes of their loved one after his or her death.

264. Furthermore, we note that the Bill will mirror the current legislation in not providing for a family veto but, we have received assurances that in practice and, as is the case under the current legislation, in cases of strong family objection, donation will not proceed.

265. We have concerns about inconsistencies in the Minister's position on this issue and how it may have influenced the evidence we have received. When speaking about the principle behind the Bill, she said the intention was to create a deemed consent system under which the role of the family would be to provide information about the wishes of

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[185] RoP, paragraph 386, 24 January 2013

[186] RoP, paragraph 387, 24 January 2013

the deceased. However, her explanation of what would happen in practice points to more of a ‘family consent’ system.

266. Within the Committee, we have different views about what the role of the family should be in relation to deemed consent; some of us favour a family veto and others favour the family being able to provide information about the wishes of the deceased. The Bill, however, and the practice that flows from it, needs to reflect the Minister’s position and to do so consistently.

267. In view of the potential for confusion between principle and practice, we recommend the Minister make a definitive statement in advance of Stage 2 proceedings, clarifying his position in relation to the role of the family in a deemed consent system.

268. Linked to this, we believe there should be closer alignment between the provision on the face of the Bill and what the Minister intends should happen in practice. We consider this would lead to greater public confidence in the opt-out system.

269. In general, we believe that, in cases where the views of the individual are known, those views should be safeguarded. However, we understand that, even in cases where those views are known, donation will not always proceed, particularly in the face of strong objections from family members. We acknowledge that this is partly because of clinicians’ duty of care towards those family members and also to preserve the integrity of the system.

270. Finally, we note the Minister’s evidence that, in practice, people whose next of kin cannot be found will not have their consent deemed. However we understand that, under the current system, it may be possible to proceed with donation in certain circumstances where family members cannot be found, albeit with some conditions imposed on that donation. We recommend that the Minister clarifies why it is not the intention for this approach to continue under any new system.

Qualifying relationships

271. In relation to the provision for qualifying relationships, we have heard much evidence about whether this list should be ranked, as is currently the case under the Human Tissue Act 2004.

272. As stated above, we believe the Bill should reflect the Minister's position in terms of the role of family. However, in our view, should the Minister confirm that the role of the family is decision-making (i.e. that persons in a qualifying relationship should have, in effect, a veto), we consider a hierarchical system of qualifying relationships must accompany this in order for the Bill to be workable. Equally, should the role of the family be to provide information, then an undifferentiated list would have the advantages identified by the Minister.

273. Finally, we believe the Minister has a duty not to legislate in such a way as to place clinicians in an uncertain position. In carrying out their work, medical staff need clarity about what they are able to do, and legal protection to do it.

274. We believe that there needs to be legal clarity for clinicians about their rights not to proceed with donation in certain circumstances. We consider such provision could be made either in the Bill or in the Code of Practice.

Consent: Adults lacking capacity

275. In relation to consent for adults lacking capacity, we have explored this issue with witnesses and the Minister, and we are satisfied that the Bill makes adequate provision in this respect.

276. Further to this, we affirm the principle that consent will not be deemed for adults lacking capacity.

Appointed representatives

Background

277. Section 7 of the Bill makes provision for an adult to appoint a representative(s) to deal with the issue of consent to donation.

278. The Bill makes provision for the appointment of representatives nominated to take decisions relating to consent after death made under either the Human Tissue Act 2004 or the Bill to be recognised in a cross border situation.[187]

279. However, the Explanatory Memorandum further states:

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[187] EM, page 76, paragraph 21

> "The only exception to this is that the effect of the appointment is different when Welsh law applies. This is because under section 7 of this Bill only the person appointed can take the decision. Under the law applicable to England if the person appointed is not available a person in a qualifying relationship can decide… Under the Bill there is no further possibility of consent being given if the appointed representative cannot make a decision."[188]

Evidence from consultees

280. A number of respondents expressed concern that, as part of the arrangements under the Bill, if an appointed representative was not available or was unable to give consent, no attempt would be made to seek consent from a person in a qualifying relationship, and that this could result in a reduction in donation rates.

281. Several respondents, including NHSBT and the HTA, told us that, in cases where an appointed representative was unable to give consent, they favoured the retention of the current system under the Human Tissue Act 2004, where "the power to make that decision can devolve down the list of qualifying relationships."[189]

282. On this point, the HTA said:

> "(…) at the moment, it is very explicit on the face of the Human Tissue Act 2004 that if that person cannot be found in the time that you need to seek consent, or if that person is unwilling to act in that capacity, then you move on to the family, so you have gone from the person's consent to the nominated representative, to the family." [190]

283. It went on:

> "In the draft legislation, there is no clarity as to what happens if that person cannot be found or that person is unwilling to act, and I know that NHS Blood and Transplant finds that particularly useful in the training of its specialist nurses to give them the confidence that as long as they have asked the

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[188] EM, page 76, paragraph 22

[189] Written evidence, HT(Org)5

[190] RoP, paragraph 243, 30 January 2013, Health and Social Care Committee

> question about a nominated representative, and if they cannot find them or they are unwilling to act, they can then move to speaking to the families. There is confidence that they are complying with the legislation."[191]

284. The BMA Cymru Wales also told us they were "concerned that where an individual has nominated someone to make the decision, and that person cannot be contacted, nobody else can give consent." [192]

285. They noted this was a change to the current arrangements in the Human Tissue Act 2004 and said "the rationale for this change is unclear (…)". [193]

286. They went on:

> "Not allowing anyone else to consent, if the nominated individual is unable to do so, increases the chance of organs being lost unnecessarily… It is also unclear how, in practice, information about the fact that someone has appointed a nominated individual would become known to the treating team."[194]

287. Further to this, NHSBT told us:

> "(…) it is not clear from the bill or the explanatory notes how the decision to appoint a representative would be recorded. We would favour regulations made under section 8(2)(b) being published to coincide with the provisions of the bill coming in to force."[195]

288. The Kidney Wales Foundation said they supported this principle of appointed representatives, "but would like to see the promotion of adopted wording for guidance throughout Wales."[196]

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[191] RoP, paragraph 243, 30 January 2013, Health and Social Care Committee

[192] Written evidence, HT(Org)18

[193] Ibid.

[194] Ibid.

[195] Written evidence, HT(Org)5

[196] Written evidence, HT(Org)26

Evidence from the Minister

289. We asked the Minister for some clarification on the arrangements for appointed representatives. She confirmed that the Human Tissue Act 2004 provided for an individual to appoint a representative to make the decision about organ donation, and that this provision would continue under the Bill. [197]

290. She acknowledged that, as now, "there exists a small risk of the appointed representative not being present at the time donation is discussed, and other family members being unaware of the appointment."[198]

291. In response to the concerns raised with us that, under the Bill, in a situation where an appointed representative was not known about, the person's consent to donation could be deemed, the Minister said:

> "We intend to allow for further clarification and safeguards of the deceased's wishes by providing for the recording of the appointed representative on the register, something which does not happen now." [199]

292. She went on:

> "However, it could be possible for an appointment to be made either orally, or in writing, and for the person not to have recorded the appointment on the register. Therefore, the communications campaign will encourage people who decide to appoint a representative to tell other family members about their decision." [200]

293. In situations where more than one representative had been appointed, she confirmed that only one of those persons needed to give consent, unless the terms of the appointment stated that they must act jointly. This, she said, was in line with guidance set out in the current Human Tissue Authority Code of Practice. [201]

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[197] Letter from the Minister for Health and Social Services, 14 February 2013

[198] Ibid.

[199] Ibid.

[200] Ibid.

[201] Ibid.

294. In cases where the appointed representative was unable to give consent, for example if they could not be contacted, the Explanatory Memorandum states "the patient's consent will not be deemed, nor would another person's consent be sought – in such instances, donation would not proceed."[202]

Our view

295. In relation to the provisions in the Bill for appointed representatives, we recognise the importance for individuals in being able to appoint a person or persons to represent them and deal with the issue of consent to donation after their death.

296. We note that, in relation to deemed consent, the ODR will not record the names of those people whose consent will be deemed. Therefore, in cases of deemed consent, the option to record a decision on the ODR about an appointed representative will not be available. However, we recognise that individuals could make other arrangements to appoint representatives either orally or in writing.

297. We welcome the Minister's intention to provide for the recording of an appointed representative on the ODR where a person has opted-in to the system. We note this option is not available currently and we consider it to be a positive development in terms of providing clarification and a safeguard of the wishes of the deceased.

298. However, we are concerned that, should an appointment be made orally or in writing (as provided for in the Bill) and not subsequently recorded on the ODR, it could be very difficult for clinicians to find out about that appointment, particularly in the time critical circumstances surrounding decisions on organ donation.

299. We note the Minister's intention that the communications campaign to accompany the Bill will encourage those people who appoint a representative to tell family members about their decision, but we recommend the Minister clarify how, in practice, clinicians will be expected to ascertain whether a person has appointed a representative to deal with the issue of consent after their death, if such appointment has not been noted on the ODR.

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[202] EM, page 15, paragraph 30

300. Further to this, we recommend the Minister consider making appropriate representations for the ODR to record representatives appointed by persons wishing their consent to be deemed.

301. Finally, we note the Minister's evidence that, in cases where an appointed representative was unable to give consent at the relevant time, donation would not go ahead. This is a departure from current practice and we agree with respondents that it could have the potential to reduce the number of organs available for donation. We consider the arrangements under the Human Tissue Act 2004 to be preferable, whereby a person in a qualifying relationship could be contacted where an appointed representative was unable to act, and we recommend that this continues in relation to the Bill.

Residency

Background

302. In relation to residency requirements, the provisions of the Bill for deemed consent apply to people who have been "ordinarily resident" in Wales for a period of at least six months before they died and who died in Wales.[203]

303. "Ordinarily resident" is not defined in the Bill. The Explanatory Memorandum states:

> "This is because ordinarily resident status needs to be assessed on a case by case basis and is primarily a question of degree and fact. The concept means a person's abode in a particular place or country which has been adopted voluntarily and for settled purpose and part of the regular order of life for the time being, whether of short or long duration."[204]

304. The Explanatory Memorandum also notes:

> "The legislation does not expressly exclude any category of person on the grounds of residency, e.g. people studying in Wales at a university or people visiting or working in Wales for six months or more. Whether individuals are considered to be resident in Wales will depend on certain criteria being met, and

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[203] EM, page 13, paragraph 24

[204] EM, page 13, paragraph 25

> will also be a matter for discussion with those closest to them, after death."[205]

Evidence from consultees

305. Some respondents drew attention to the potential difficulties in establishing whether a person had been ordinarily resident in Wales for the requisite period prior to their death, and asked whether this could add additional burdens and time constraints on clinicians.

306. Dr Dariusz Tetla said:

> "The coexistence of two different systems within the UK will require clear identification [of] who is or who is not permanent resident in Wales, especially if no relatives of a deceased person are available. In relation to subsection (3)(a) (b) of section 3 - it is important to identify valid consent for removal of the tissue, obtained in the country where the relevant material was imported from, and the evidence exists to prove it."[206]

307. Cardiff and Vale University Health Board Organ Donation Committee highlighted the role of the family in determining residency, saying:

> "There are concerns as to how the SNODS would be able to accurately identify residency of the potential donor (…) without speaking to the relatives."[207]

308. They went on:

> "One of the benefits of the Bill is seen to be that the introduction to the conversation with the relatives would include the fact that the potential donor hadn't opted out, but this would not apply to those not resident in Wales and therefore it won't be possible to start the conversation with the fact that they hadn't opted out prior to establishing residency. NB this may have considerable implications for litigation."[208]

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[205] EM, page 13, paragraph 24
[206] Written evidence, HT(Org)14
[207] Written evidence, HT(Org)12
[208] Ibid.

309. Sally Johnson from NHSBT told us:

> "I think that it is possible to work with the families to determine whether they believe that they are ordinarily resident in terms of the way in which it is set out (…). It is not something that I think our specialist nurses would make a definite determination on; they would be guided by the families. I would not want to put them in a position where they had to say that someone is ordinarily resident, if the family said that they were not."[209]

310. The RCN told us they had "significant concerns" that the arrangements and tests for establishing residency were "not clear enough to deal with cross-border challenges."[210]

311. They went on to say:

> "There is not sufficient detail in the Draft Explanatory Memorandum on safeguards that need to be in place to deal with issues arising from diverse cultural models of residency. For example, given the significance placed in the proposals on residency, the Explanatory Memorandum should acknowledge the importance of, and anticipate strategies for, specific engagement with the gypsy and traveller community."[211]

Evidence from the Minister

312. On the question of the threshold for residency being set at six months, the Minister told us:

> "We consulted very specifically on the length of time in the White Paper. We also asked that very specific question in the consultation on the draft Bill, and no compelling arguments were put forward against that specific amount of time."[212]

313. We asked the Minister whether the residency requirements in the Bill would capture students and prisoners. She confirmed that they would, provided they had been here for six months, and that the

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[209] RoP, paragraph 577, 30 January 2013, Health and Social Care Committee

[210] Written evidence, HT(Org)15

[211] Ibid.

[212] RoP, paragraph 377, 24 January 2013, Health and Social Care Committee

education and communication campaign would need to cover this. She also said that “they would have the safeguard of their family as well.”[213]

314. Further to our questions about whether the Bill would apply to certain, distinct groups such as students, the Minister’s policy official told us:

> “(…) the Bill does not exclude anyone specifically, but the concept of “ordinarily resident" comes into play. Although you would have had to reside in Wales for six months not to be excluded straight off, there are people who might have lived here for six months or more but do not necessarily consider themselves to be ordinarily resident in Wales. (…) [The Bill] could potentially cover all of those groups, but, in reality, it is necessary to have a conversation with the family to determine whether or not the person’s residence in Wales had that quality of being ordinarily resident.”[214]

315. In relation to persons with no fixed address, the Minister’s policy official confirmed that consent could not been deemed in such cases. He went on:

> “We have been talking with some of the stakeholder groups that work with homeless people and the like. They say that the sad fact is that these people are unlikely to die in circumstances where their organs would be available for transplantation, and that they probably suffer quite a lot of ill health. If people are homeless, you may not be able to reach their families. This goes back to the role of families as important safeguards.”[215]

316. Specifically on the application of the Bill to prisoners, we asked the Minister whether there were any particular ethical issues in deeming the consent of prisoners, who were not in the country of their own choosing.

317. On this point, the Minister said:

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[213] RoP, paragraphs 376 and 379, 24 January 2013 and paragraph 98, 20 February 2013, Health and Social Care Committee

[214] RoP, paragraph 380, 24 January 2013, Health and Social Care Committee

[215] RoP, paragraphs 389 and 392, 24 January 2013, Health and Social Care Committee

> "I do not propose to amend the Bill [to exclude prisoners] for the simple reason that it is not possible to define and seek to exclude certain categories of person in the way suggested. The issue becomes complex if exceptions are to be considered – for example, would length of sentence have to be considered; other persons may be detained under other circumstances such as secure mental health facilities, or indeed other scenarios we have not yet envisaged of people being in Wales through no choice of their own." [216]

318. She continued:

> "I believe the most straightforward answer is to retain the concept of "ordinarily resident" which together with the conversation with the family will allow cases to be considered individually. To make an exception here may have unintended consequences on other policies. I believe the overriding principle should be to make those who reside in Wales, whether in prison or not, subject to Welsh laws. In addition, prisoners should be afforded the same choices in relation to organ donation as the rest of the population."[217]

Our view

319. In relation to residency, we have had some discussions about what would constitute a sufficient period of time for a person to have been ordinarily resident in Wales before their consent to donation could be deemed in accordance with the Bill. There were some concerns amongst Members that the six-month period provided for in the Bill was not necessarily sufficient, although we did not come to a firm view on this.

320. We acknowledge the potential challenges for clinical staff in resolving questions of residency in certain cases, and that these challenges could be all the more so in cases involving persons with diverse cultural models of residency, such as gypsy and traveller communities. We draw this point to the Minister's attention.

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[216] Letter from the Minister for Health and Social Services, 28 February 2013

[217] Ibid.

321. We recognise the importance of the conversations between clinical staff and families in resolving any questions about residency.

322. Finally, we believe the Bill should recognise that there will be residents in Wales who are not here voluntarily, for example, prisoners and some armed forces personnel from outside Wales. Indeed, the Explanatory Memorandum refers to the concept of 'ordinarily resident' as meaning "a person's abode in a particular place or country which has been adopted voluntarily". We are not convinced that the Bill should apply to these people and we are puzzled by the Minister's argument that it would not be possible for the Bill to specifically exclude certain categories of people because it already does so in relation to individuals under the age of 18. We recommend the Minister give further consideration to this matter.

323. We would prefer those individuals from outside Wales who are not resident in Wales voluntarily to be treated in the same way as those who are not ordinarily resident here, i.e. able to opt in but not to be regarded as having deemed their consent.

324. We also have concerns in relation to the application of the Bill to students, particularly international students. We have concerns about how such students will be made fully aware of any new system and we wish to highlight the particular practical challenges in contacting the families of international students in the time-critical circumstances surrounding decisions on organ donation. We recommend the Minister give further consideration to this matter.

Coroner permission

Background

325. Section 13 of the Bill makes provision in relation to coroners and replicates the effect of section 11 of the Human Tissue Act 2004.[218]

326. The Explanatory Memorandum states that, in order to maintain the current legal position regarding coroners, section 13 exempts from the requirements of the Bill anything done for the purposes of the functions of a coroner, or under his authority.[219]

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[218] EM, page 80, paragraph 40

[219] Ibid.

Evidence from consultees

327. We heard evidence that the Bill provides for a regime which is supportive of donation after circulatory death (DCD), but then ensures that such a regime cannot be successfully implemented within the necessary timescales because of the requirement to obtain coroner consent.

328. The BTS said that, in those cases where it was necessary to obtain consent from the coroner before retrieving organs, it would be helpful if steps could be taken to preserve the organs for transplantation while consent was being sought:

> "Currently in the UK, there is only one active programme where organ donation occurs from the emergency department… In that setting, you have someone who has suffered a sudden death and is therefore under the coroner's jurisdiction. If you wanted to intervene to preserve the organs until such time as we have consent from the relatives you need permission from the coroner to proceed, because it is up to him as to whether this sudden death means that there has to be an inquest and he wants the body to be untouched (…)."[220]

329. The BTS also said it would be helpful if what constituted 'minimal steps' for the preservation of organs was clarified:

> "There are certain things that we could do to preserve organs. (…) The Human Tissue Act 2004 talks about minimal steps but does not define them clearly, but there are minimal steps to be taken, depending on the different organs."[221]

330. They went on:

> "There is a phrase about the coroner in the Bill—section 13(3), which says that the consent of the coroner is required before the person may act on authority for the preservation of organs for transplantation. If we have to wait for the coroner to do that, there will be a delay. If the Bill allowed us to take minimal

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[220] RoP, paragraph 185, 30 January 2013, Health and Social Care Committee
[221] Ibid.

> steps up until getting the coroner's permission to remove the organ, that would be helpful."[222]

Evidence from the Minister

331. The Minister told us that the Bill makes no changes regarding the role of the Coroner, and that section 13 of the Bill replicates the effect of section 11 of the Human Tissue Act 2004.[223]

332. She explained that, in certain cases, the person's death may come under the jurisdiction of the Coroner and so donation cannot go ahead without his or her agreement. This, she said, could include the steps necessary to preserve part of a body for transplantation.[224]

333. She continued:

> "The Bill does not change the timescales involved in this process and hospitals will already have local arrangements in place with their Coroner, which I expect to continue."[225]

334. In later correspondence, she told us:

> "The current Human Tissue Authority Code of Practice 2 (…) contains guidelines for what should happen where a person dies suddenly and uncontrolled non-heart beating donation is a possibility. Consulting the Coroner about such cases is already an established part of the process and the question of delay because of the Coroner is not an issue since the requirements of the Coroner must be satisfied first. The current law, as well as the new one, allows clinicians to take the minimum steps necessary (subject to the Coroner's consent where required) to preserve organs, using the least invasive procedure, whilst the question of consent is established."[226]

335. We put some concerns to the Minister about the potential for interventions in order to preserve organs being performed on an individual and then stopped by a Coroner, making those interventions unnecessary.

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[222] RoP, paragraph 191, 30 January 2013, Health and Social Care Committee
[223] Letter from the Minister for Health and Social Services, 14 February 2013
[224] Ibid.
[225] Ibid.
[226] Letter from the Minister for Health and Social Services, 28 February 2013

336. Responding to this, she said:

> "The HTA guidelines make clear that the Coroner must be informed and advised at the point the potential donor is identified. The specialist nurse liaises with the Coroner's officials on all these matters. If a Coroner requires a post mortem, then this decision will be communicated quickly and perfusion and organ donation would not then be allowed to proceed. However, the Coroner may exercise discretion in favour of permitting perfusion subject to further investigations. It is perhaps possible for perfusion to be ceased in light of those further investigations, however, that is what happens now and our proposed legislation does not change this process."[227]

Our view

337. We acknowledge the Minister's evidence that the Bill makes no change to the existing law in relation to those cases where consent from a coroner must be obtained prior to the removal of organs for transplantation.

338. We also acknowledge that the Bill makes no change to the timescales involved in this process, and that this will continue to be a matter to be managed by means of local arrangements between hospital staff and coroners.

339. We note that consultation between medical teams and coroners, where appropriate, is part of current, established practice and we see nothing in the Bill that should prevent this from continuing in the future.

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[227] Letter from the Minister for Health and Social Services, 28 February 2013

6. Registration system

Background

340. Any change in the arrangements for consent to organ donation in Wales would require a corresponding change to the current organ donation registration system.

341. The Explanatory Memorandum states that the new system "will need to be able to link with register arrangements for the rest of the UK to ensure no wishes are missed (…). It will also be important for the systems to map across to ensure no-one has registered a conflicting wish."[228]

342. The Explanatory Memorandum goes on to state that a review commissioned by the Welsh Government suggests that "the best way of achieving all these requirements is a comprehensive redevelopment of the ODR to meet the legislative needs of all parts of the UK in an integrated way" and that the Welsh Government is discussing this proposal with the other governments in the UK.[229]

Evidence from consultees

343. On this matter, we heard evidence from a number of respondents, most of whom expressed broad support for the redevelopment of a UK-wide registration system.

344. Cardiff and Vale University Health Board Organ Donation Committee stated that it was "imperative" that there is only one UK-wide register to ensure that opposing views are not logged on different registers. [230]

345. Dr Peter Matthews of the ARCW said:

> "It would be more sensible to have a single register run by NHS Blood and Transplant to cover the whole of the UK. That will get around some of the issues as to whether people in Wales

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[228] EM, page 14, paragraph 28

[229] Ibid.

[230] Written evidence, HT(Org)12

> who have opted out end up dying in another part of the UK. To run two separate registers is likely to lead to trouble."[231]

346. In their evidence, the HTA suggested that the Welsh Government's proposal of a register that would allow Welsh residents to both opt in and opt out of organ donation is fundamental in guaranteeing that the wishes of the deceased in life remain paramount.[232]

347. It went on to say that such a register would:

> "(…) allow the HTA to have greater confidence when drafting a Code of Practice including guidance on deemed consent in Wales, as the practical issues could be clearly addressed and advice provided on what steps should be taken in given circumstances."[233]

348. The HTA clarified this further by saying that the absence of such a register could increase confusion and uncertainty within the proposed system, and had the potential to cause the provision of unclear and unhelpful advice.[234]

349. The British Heart Foundation, believed that the existence of a core central agency overseeing organ donation was one of the keys to success. However, it stated that it was not clear how the Welsh Government and NHSBT would work alongside each other to ensure a smooth transition from the current to the new registration system.[235]

350. The evidence submitted by the Clinical Ethics Committee of Abertawe Bro Morgannwg University Health Board, whilst supportive in principle of a redeveloped ODR system, also drew attention to the potential for unintended consequences, saying:

> "The EM says that the existing partnership arrangements (DVLA, Boots and Facebook) will continue to allow an opt in but not an opt out. This asymmetry is ethically problematic because it could lead people who consider registering in those ways to believe that by not opting in they are implying that

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[231] RoP, paragraph 122, 30 January 2013, Health and Social Care Committee
[232] Written evidence, HT(Org)27
[233] Ibid.
[234] Ibid.
[235] Written evidence, HT(Org)21

> they do not wish to donate. This arrangement undermines the intended assumption that someone who has expressed no wish did not object. The partnership arrangements should be changed so as to allow access to the Welsh register either to opt in or opt out."[236]

351. Dr Dariusz Tetla had concerns that the new system has the potential to be very complicated, and may lead to the action of determining a person's wishes taking a longer period of time than at present.[237]

352. Professor John Saunders also expressed concerns about the practical implementation of a new ODR across the UK. In his evidence, he drew attention to the difficulties in monitoring cross-border migration and the ability to keep the register up-to-date, and the potential for negative media coverage in the event of any human errors in operating the system.[238]

Evidence from the Minister

353. During the Minister's first appearance before the Committee on 24 January she confirmed that her preference was for a single UK-wide register "that will meet the requirements of each of the four UK countries".[239]

354. The Minister went on to say that a single register had been "accepted in principle" by NHSBT, and that she had written to her counterparts in Scotland, Northern Ireland and England to canvass opinion and support for the suggestion of the redevelopment of the ODR and request monetary contributions.[240]

355. On this point, NHSBT (who are responsible for the organ donor register) told us that they welcomed the commitment from the Welsh Government in terms of financing the redevelopment of the register and the implementation of the system.[241]

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[236] Written evidence, HT(Org)26
[237] RoP, paragraph 132, 30 January 2013, Health and Social Care Committee
[238] RoP, paragraphs 283-284, 7 February 2013, Health and Social Care Committee
[239] RoP, paragraph 460, 24 January 2013, Health and Social Care Committee
[240] Ibid.
[241] Written evidence, HT(Org)5

356. In relation to the timescale for development and implementation of the new ODR, NHSBT said:

> "I think that it is practical and achievable, provided that getting a decision from all four Governments about buying into a single new register, which is the only safe way of doing it, does not eat up all the contingency in our plans. So, we need to know soon; I would say that we need to know definitely by the end of February if we are to meet the expected timetable."[242]

357. In later evidence, the Minister said:

> "I have had a response from the Minister in Scotland, who is very happy and positive in support of that. We are viewing all options with counterparts at the moment because I would like to get that up and running certainly by next month."[243]

358. The Minister subsequently confirmed that all three of her counterparts have accepted the 'one register' suggestion in principle. She added that officials would be meeting shortly to discuss the issue further.[244]

359. In later correspondence, the Minister provided further information regarding the plans for the redevelopment of the organ donation registration system. She confirmed that, under the new registration system, people will have a choice to either register a wish to be a donor, register a wish not to be a donor or do nothing, in which case their consent may be deemed to have been given. She also confirmed that the register will not record people whose consent will be deemed.[245]

360. In terms of people who have currently opted-in to the ODR in Wales, the Minister stated that it was the Welsh Government's intention for those people to be contacted and asked to confirm their decision in light of the new legislation.[246]

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[242] RoP, paragraph 575, 24 January 2013, Health and Social Care Committee

[243] RoP, paragraph 460, 24 January 2013, Health and Social Care Committee

[244] RoP, paragraph 128, 20 February 2013, Health and Social Care Committee

[245] Letter from the Minister for Health and Social Services, 14 February 2013

[246] Ibid.

361. The Minister added that one of the key issues faced by her and her officials was ensuring that a decision to opt out taken by a Welsh resident was available to clinicians in other parts of the UK, as any recorded decision of the deceased will have to be taken into account under the Human Tissue Act 2004 and the Human Tissue (Scotland) Act 2006. She stated that having a single register for the whole of the UK, capable of showing these details, would resolve this situation.[247]

362. Finally, we asked the Minister whether the ODR would give people the opportunity to record their wish to donate some but not all of their organs. Responding to this, the Minister's policy official told us:

> "As it stands now, when you go to register it says, "Do you wish to register?", and "Do you wish to deselect any of the following list of organs?" People can choose if, for example, they do not want the heart or liver to be used. [Under the Bill] That would be the same—people could still opt in, but then opt out of individual organs and tissues."[248]

363. Further to this, the Minister stated:

> "The list as it stands now will be the same. If you are opting in you will tick the list. If it is deemed consent, it will be presumed that the whole of the list applies."[249]

Our view

364. In relation to the registration system for organ donation, we recognise the importance of the organ donor register (ODR) in being an accurate and reliable record of an individual's wishes, and in guaranteeing that the wishes of the deceased in life remain paramount.

365. We note that there is broad support for the redevelopment of the organ donation registration system. As such, we are content with the Minister's plans for a single organ donation register that captures both the UK-wide opt-in registration system and any new deemed consent system that might operate in the future in Wales. However, whilst

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[247] Letter from the Minister for Health and Social Services, 14 February 2013
[248] RoP, paragraph 328, 24 January 2013, Health and Social Care Committee
[249] RoP, paragraph 330, 24 January 2013, Health and Social Care Committee

supportive of the plans in principle, we believe the Minister needs to undertake some further work on this matter.

366. Whilst noting the Minister's evidence that all three of her counterparts have accepted the principle of a single ODR for the UK, we recommend the Minister provide more information regarding the discussions with the other UK Governments on this matter. In particular, we seek assurances from the Minister that the preferred option of a single ODR is deliverable, as it is dependent on the agreement of the other governments within the UK.

367. We recommend the Minister provide further information on the estimated costs involved in developing and implementing a single ODR, and what monetary contribution the Minister expects to receive from the other governments within the UK.

368. We wish to draw the Minister's attention to the evidence we have received about possible unintended consequences associated with any new ODR, including the dangers of out-of-date information being recorded and the subsequent potential for negative media coverage, as well as the difficulties in monitoring cross-border migration. We seek further information from the Minister about the transitional arrangements that will be put in place to ensure the accuracy of the information on any new ODR.

369. In relation to individuals being able to choose to donate some but not all of their organs when registering with the ODR, we note that deemed consent will apply to all organs on the ODR list. Any person wishing to donate certain organs will have to expressly opt in and then select those organs to donate from the available list. We recommend that, as part of the education and communications campaign to accompany the Bill, the Minister should ensure that this matter is clearly explained and that people are aware of the options available to them, including the option to record an appointed representative on the ODR in cases of deemed consent (see paragraph 300).

370. Finally, one member of the Committee believed that the ODR should be able to record people's wishes to opt out in Wales but opt in to the UK-wide system as a means of recording their opposition to the principle of deemed consent in Wales. The other members of the

Committee were of the view that this matter would be better dealt with by appointing a representative.

7. Communication and education

Background

371. Section 2 of the Bill places a duty on Welsh Ministers to promote organ donation, and to provide information about and increase awareness of transplantation activities.

372. The Explanatory Memorandum states that an extensive publicity and engagement campaign, consisting of five phases, will form part of the implementation of the new legislation and beyond.[250]

373. The Regulatory Impact Assessment (RIA) identifies that £2.9 million over ten years will be spent on communications and an additional £25,000 in 2015-16 and £50,000 per annum from 2016-17 onwards to notify 17 year olds of the law which will apply when they turn 18.[251]

374. In order to measure the effectiveness of the communications campaign and to test the population's awareness, understanding and attitudes towards the legislation, the Minister has commissioned the collection of data from questions within the Wales Omnibus Survey from 2012-16.[252]

375. The Minister has told us that, in order for the principle of deemed consent to be valid, people in Wales must be "fully aware" of the system; the options they have to express consent (i.e. to opt in or to opt out); or for them to take no action and their consent to be deemed.

376. Chapter 12 deals in more detail with evaluating the success of the legislation.

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[250] EM, page 23, paragraph 57
[251] EM, page 45, RIA Appendix 1
[252] EM, page 23, paragraph 61

Evidence from consultees

Effective communication and education

377. The majority of respondents stated that the communication and education campaign was crucial to ensuring that people were aware of the new legislation.

378. On this point, the HTA stated that "communication will be vital in ensuring the legitimacy of a system of deemed consent, in the sense that without it Welsh residents will not know what action they are required to take in order [to] not have their consent deemed".[253]

379. They added:

> "(…) in order to maintain the legitimacy of a system of deemed consent there will need to be a continuous communication programme, so those that have made a decision in the past are able to revisit it if they wish."[254]

380. This was echoed by the UKDEC, who stated:

> "The Bill, and its associated Explanatory Memorandum, acknowledges the communications and educational challenges inherent in a switch to a system of deemed consent. From an ethical perspective, clear information about the system and the implications of opting out or not, is clearly a vital component of an ethically acceptable system".[255]

381. The BTS stated it was "delighted" to see that the Welsh Ministers were planning on promoting the deemed consent system. The BTS said:

> "There is a similar requirement in the Human Tissue (Scotland) Act 2006 to "promote, support and develop programmes of transplantation" as well as to "promote information and awareness about the donation for transplantation of parts of a human body", and the public awareness campaigns in Scotland

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[253] Written evidence, HT(Org)27

[254] Ibid.

[255] Written evidence, HT(Org)4

> have resulted in high rates of registration on the Organ Donor Register and a higher rate of consent to organ donation."[256]

382. In addition, Kidney Wales Foundation pointed to another international comparison:

> "One of the lessons from the successful implementation of opt-out legislation in Belgium in 1986 was the factual dissemination of the issues and the opposition to those [who] prayed on human fears of death and human organ retrieval."[257]

383. In view of the importance of people being aware and sufficiently informed about the proposed deemed consent system, Dr Dariusz Tetla suggested that the promotion of organ donation should become an obligatory part of educational programmes.[258]

384. Patient Concern, however, were not convinced that the communication campaign would be effective. They told us:

> "The idea that any amount of publicity will ensure that everyone fully understands their options and the need to exercise them is fanciful."[259]

Reaching all sections of society

385. While stakeholders generally welcomed the Minister's commitment to engage with all sections of society in Wales, a number of them expressed concerns about the effectiveness of the communication campaign in doing this.

386. Sense and DeafBlind Cymru told us that, although it welcomed the references to people with single sensory loss:

> "(…) we are not reassured that the communication plan has addressed deafblind people and believe it might not have paid due regard to them. Therefore, we would recommend that people with dual sensory loss are treated as a unique group as

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[256] Written evidence, HT(Org)7
[257] Written evidence, HT(Org)25
[258] Written evidence, HT(Org)14
[259] Written evidence HT(Org)6

> well as blind and partially sighted people and people who are deaf or hard of hearing."[260]

387. The British Heart Foundation Cymru believed it was particularly important that the Welsh Government engaged with the Black and Minority Ethnic (BME) community, as this community was known to have significantly low levels of donation.[261]

388. The Royal College of General Practitioners also commented on the issue of reaching all sections of society. It said:

> "Patients whose first language is not English or Welsh will need special consideration as they may not understand the implications and special consideration needs to be given to those whose religious or cultural beliefs prevent removal of tissue and organs after death."[262]

389. In addition, the RCN suggested that special thought should be given to providing clear and targeted information to the student population in Wales.[263]

The costs of the communication campaign

390. In relation to the costs of the communications campaign, a number of stakeholders suggested that it would be more effective to use the funding to raise awareness and promote the current system.

391. The Muslim Council of Wales suggested that many people in the Muslim community were willing to donate but were unaware of how to do so. Mr Kidwai believed that education and an awareness of the need for organ donors and how to become an organ donor can more effectively increase donation rates in Wales while avoiding the "legal, ethical and moral quagmire of the presumed consent system".[264]

392. The Society for the Protection of Unborn Children had similar views*:*

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[260] Written evidence, HT(Org)16
[261] Written evidence, HT(Org)21
[262] Written evidence, HT(Org)22
[263] Written evidence, HT(Org)15
[264] RoP, paragraph 156, 7 February 2013, Health and Social Care Committee

> "Given that the Government is committed to the expense of a programme of public education, would it not make more sense, especially given the poor likelihood of success of an opt-out system, to implement an education programme directed at enhancing people's free choices to participate in organ donation."[265]

393. In his evidence, Professor John Saunders stated:

> "At the moment, if you were to ask me what my prediction would be and what my crystal ball gazing would reveal, I would say that I do not think that this will damage the situation. I do not think that there will be a great fall-off in transplants. However, I am not convinced that there will be an increase. I suspect that we will be much where we were beforehand."[266]

394. In written evidence the HTA questioned whether £50,000 per annum from 2017-18 would be enough for on-going communication. HTA said it had concerns that this figure was quite low for such a vital issue, and went on to state:

> "The HTA also questions whether an overall communications spend of £2.9m over ten years is adequate for such a significant legislative and operational change on a sensitive and complex issue."[267]

395. In attempting to compare the funding levels with that of other, comparable campaigns, the HTA stated that:

> "(…) as far as I recall, the Department of Health's Change4Life programme had a marketing budget of £14 million for just one year, 2011-12. Of course that covers England, which has about 10 times the population of Wales, but that is still just in one year. So, that figure of £2.9 million seemed, to us, to be very much on the low side, given the criticality of the communication."[268]

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[265] Written evidence, HT(Org)20
[266] RoP, paragraph 288, 7 February 2013, Health and Social Care Committee
[267] Written evidence, HT(Org)27
[268] RoP, paragraph 200, 30 January 2013, Health and Social Care Committee

Evidence from the Minister

Effective Communication and education

396. In relation to the need to communicate any changes in the law to the public, the Minister's legal adviser told us:

> "(…) consent cannot be deemed if people do not understand the system. We recognise that consent can only be lawful if people have full knowledge of the system, and full knowledge of what they are actually consenting to by doing nothing and taking no action."[269]

397. She continued:

> "Consent could not be valid if people did not understand the system; it would be in breach of human rights."[270]

398. We wrote to the Minister for clarification of this point, asking her to set out what she considered to be the requisite level of public understanding in order to achieve satisfactory compliance with Human Rights legislation. In response, the Minister re-iterated the points made in oral evidence that:

> "In a deemed consent system individuals need to be fully aware of the need to consent or object to an action and be fully aware of the consequences."[271]

399. She noted that articles 8 and 9 of the European Convention on Human Rights (ECHR) provide a right to respect for private and family life and to freedom of thought, conscience and religion, and that these are qualified rights that require "a balance between the rights of the individual and the needs of the wider community".[272]

400. She went on to say that, as part of the requirements inherent in articles 8 and 9, there was a need for "widespread consultation before introducing legislation and this has been done. There is also a need for a sufficient period of adjustment after the legislation is made to allow it to gain public consensus and bed in. That is why there is a two

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[269] RoP, paragraph 17, 20 February 2013, Health and Social Care Committee
[270] RoP, paragraph 19, 20 February 2013, Health and Social Care Committee
[271] Letter from the Minister for Health and Social Services, 28 February 2013
[272] Ibid.

year period after the legislation is made and before the new system goes live when a significant awareness raising campaign will be undertaken."[273]

401. The Minister also stated that a recent review of European case law had "not identified any cases where deemed/presumed consent legislation (and/or practice) has been challenged either on grounds of interference with article 8 or article 9 rights or otherwise."[274]

402. She went on to state:

> "I am progressing the Bill in such a way as to ensure compliance with the Convention including adequate safeguards in respect of consent choices available, family involvement to ensure wishes and beliefs are respected and appropriate arrangements in respect of vulnerable adults and children."[275]

403. Expanding on her plans for an awareness raising campaign, the Minister told us:

> "Section 2 of the Bill places a duty on the Welsh Ministers to inform the public of the circumstances in which consent to organ and tissue donation will be deemed. Taking a measured and proportionate approach, the Welsh Government proposes to write to every household in Wales about the soft opt-out system of organ and tissue donation and the choices available to individuals who live in Wales."[276]

404. She said that this work would take place during the spring of 2014 and the summer of 2015.[277]

405. She went on to say:

> "We are currently consulting media planners to ensure that the advertising and communication is as effective as possible. Advertising activity will take place every six months and will last approximately four weeks. It will consist of an advertising campaign (radio adverts, outdoor, digital, social media) to

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[273] Letter from the Minister for Health and Social Services, 28 February 2013

[274] Ibid.

[275] Ibid.

[276] Letter from the Minister for Health and Social Services, 12 March 2013

[277] Ibid.

> provide information, alongside the stakeholder and community engagement. Consideration will also be given to TV advertising taking into account audience reach and value for money. A combination of other advertising and direct marketing may guarantee a more targeted approach."[278]

406. The Minister went on to say:

> "Other free communication opportunities will be investigated such as partnerships with local authorities and information on organ donation included in regular mailings such as council tax statements. (…) Working with Welsh Universities, there may also be long term free opportunities by including information through UCAS for students when applying to universities in Wales. Discussions will take place with the Department for Education and Skills on distributing information through Personal Health and Social Education or equivalent lessons to young people at GCSE ages."[279]

407. Further to this, the Minister told us the communications campaign would be subject to monitoring, evaluation and refinement to ensure the message was being understood.[280]

408. On the subject of monitoring the campaign, the Minister said:

> "(…) we will have an evaluation strategy to monitor the accessibility of the communications programme. We will have a public attitude survey, and that will be repeated and the results published as we go from 2013 to 2016. Also, by monitoring public awareness, by monitoring people's understanding of the legislation, and by monitoring attitudes, we can ensure that our communications strategy and our education strategy can be strengthened if needed."[281]

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[278] Letter from the Minister for Health and Social Services, 12 March 2013

[279] Letter from the Minister for Health and Social Services, 28 February 2013

[280] Ibid.

[281] RoP, paragraph 32, 20 February 2013, Health and Social Care Committee

409. The Minister confirmed that her officials were working on the draft evaluation strategy, and that she would share this with Members when it was available.[282]

Reaching all sections of society

410. With regard to disseminating information about a new deemed consent system to all sections of society, the Minister told us that different methods would be used to reach different communities, for example, more visual material, attending freshers' fairs or engaging with community leaders.[283]

411. The Minister also said:

> "There will be a lot of focused publicity with, for example, faith groups, or hard-to-reach groups (…)."[284]

412. In later evidence to us, the Minister stated:

> "It is important that we reach all parts of society (…) Officials have had a lot of discussions with a number of non-governmental organisations to ensure that we can reassure people and that we can use agencies that they trust in order to get that information out. That is why we have this long, two-year period. There are specific groups that we are considering and we have engaged professional advisers on both general communications and faith groups, and it is something that we are very aware of."[285]

413. She said that "specific actions will bring the soft opt-out system to the attention of people reaching the age of 18, students and people migrating to Wales". [286]

414. She went on:

> "(…) work will also be undertaken to ensure hard to reach groups can access information."[287]

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[282] RoP, paragraph 160-161, 20 February 2013, Health and Social Care Committee
[283] RoP, paragraphs 291 and 376, 24 January 2013, Health and Social Care Committee
[284] RoP, paragraph 290, 24 January 2013, Health and Social Care Committee
[285] RoP, paragraphs 198-199, 20 February 2013, Health and Social Care Committee
[286] Letter from the Minister for Health and Social Services, 12 March 2013

The costs of the communication campaign

415. We asked the Minister whether she could achieve better value for money in increasing donor numbers by spending the £2.9 million on a publicity campaign around the current scheme. She told us that she did not think so:

> "We have had very good publicity campaigns following the organ donation taskforce and its recommendations that have been implemented. So, we have tried that. Having said that, I do not think that any one thing works, even this system will not give us all the donors that we would like. It is a matter of having lots of different strings to the bow, to pull together."[288]

416. In relation to the level of funding that had been put aside for communication, the Minister stated:

> "At the stage that we are now, we think that the budget that we have set aside is adequate. It has been based on our best assessment of what the communication and education requirements are, but we will obviously have to keep the matter under review as we go forward."[289]

417. In assessing costs, she drew attention to the communication campaign that took place prior to the ban on smoking in public places in Wales.[290]

418. When questioned on the appropriateness of the comparison with the ban on smoking in public places in terms of the validity of the assessments as a basis for communicating a change to the system of organ donation in Wales, the Minister said:

> "The comparisons I made in Committee to the communication strategy for the implementation of the ban on smoking in public places were intended only to illustrate the high levels of awareness and message penetration achieved by the communications work delivered by the Welsh Government. The budget used for the public information campaign for the

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[287] Letter from the Minister for Health and Social Services, 12 March 2013
[288] RoP, paragraph 298, 24 January 2013, Health and Social Care Committee
[289] RoP, paragraph 22, 20 February 2013, Health and Social Care Committee
[290] RoP, paragraph 26, 20 February 2013, Health and Social Care Committee

> smoking legislation was approximately £1.318 million in the year prior to implementation. The ban came into force in April 2007. We achieved a 98 per cent awareness rate."
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> "In comparison, the Human Transplantation (Wales) Bill proposes an even greater budget. We propose to spend £318,000 in the year of Royal Assent (for planning assumptions, this coming financial year), increasing to £808,000 next year prior to implementation and £1.453 million in 2015. The figure for 2015/16 allows a budget for direct mailing to all households to all households in Wales immediately prior to the introduction of the new system."[291]

419. In addition, the Minister told us that the Heart to Heart roadshow, which ran from 25 January – 14 February 2013, had cost approximately £20,000.[292]

Our view

420. The communication and education campaign that will precede the implementation of the Bill, if enacted, will be vital in terms of ensuring the public's understanding of a deemed consent system for organ donation in Wales.

421. Furthermore, that campaign will be critical in meeting the Minister's own test that "in a deemed consent system individuals need to be fully aware of the need to consent or object to an action and be fully aware of the consequences" of the legislation in order to comply with Human Rights law.

422. We have considerable concerns about this. **We recommend the Minister provide more information in relation to his test that "in a deemed consent system individuals need to be fully aware of the need to consent or object to an action and be fully aware of the consequences" and, in particular, how he intends to meet that test.**

423. The campaign proposed by the Minister is a significant undertaking for him and his team. We agree with respondents that there are clearly many challenges involved in communicating a message of this importance on this scale, particularly in terms of

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[291] Letter from the Minister for Health and Social Services, 28 February 2013

[292] Ibid.

engaging with people whose first language is not English or Welsh and communities that are traditionally hard to reach or have particular needs relating to accessibility.

424. We note the Minister's intention to produce an evaluation strategy for monitoring the effectiveness of the campaign, and to publish public attitude survey results as the campaign progresses. We are pleased that he intends to use this information to strengthen the evaluation strategy if necessary.

425. In relation to the costs of the campaign, we have concerns about the amount of money the Minister has allocated for this. We note that the budget has been based on a similar campaign prior to the introduction of the ban on smoking in public places in Wales, and that more money has been set aside for the campaign on the Bill. Nevertheless, we are not persuaded that this provides an adequate basis for comparison.

426. Furthermore, we remain to be convinced that the level of resources allocated by the Minister for the campaign will be sufficient to meet the Minister's own test that every person must be "fully aware" of any new system.

427. We recommend the Minister give further thought to the level of funding required for such an extensive communication and education campaign.

428. However, some members of the Committee were of the view that the policy objectives of the Bill could be better achieved if the resources allocated to it were used in other ways, for example, for a refreshed and re-targeted drive to increase donations under the current system. We recognise that any adjustment to the resource allocation for a communications campaign to accompany the Bill may serve only to strengthen these views.

8. Training

Background

429. Sections 14 and 15 of the Bill make amendments to the Human Tissue Act 2004. In particular, they will enable the production of codes of practice and other guidance and information regarding a deemed consent system to persons involved in transplantation activities.

430. With regard to ensuring that doctors, nurses and other clinicians are aware and able to perform their roles within a deemed consent system, the Regulatory Impact Assessment (RIA) identifies that £224,000 in 2014-15 and £100,000 in 2015-16 will be spent on clinician training.[293]

431. The Explanatory Memorandum states that, in addition to Welsh NHS staff, it will also be important for NHS staff in England, Scotland and Northern Ireland to be aware of the arrangements for deemed consent in Wales.[294]

Evidence from consultees

432. A number of stakeholders highlighted the importance of adequate training and the need for it to be provided to different sectors in and outside of Wales.

433. In oral evidence the HTA stated that "training is fundamental to a successful system".[295]

434. In oral evidence NHSBT commented on how training would be required to ensure that the way in which families are approached is done correctly :

> "When we approach a family in a situation of deemed consent, I would expect that we would also be saying that the assumption is that the person wanted to be an organ donor and, therefore, we would be seeking the family's support, rather than approaching it in a more neutral way, as we currently do (…) [There are] a huge number of people who need to understand

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[293] EM, page 45, RIA Appendix 1

[294] EM, page 21, paragraph 51

[295] RoP, paragraph 198, 30 January 2013, Health and Social Care Committee

> the implications of the Bill and how best to approach families if we are to make it successful."[296]

435. The UKDEC stated that adequate training and support will need to be provided to professionals to ensure there is trust in the system:

> "Training and support for professionals will also be a key element in ensuring trust in the new system – if the new system is perceived as too complicated this could undermine trust in both professionals and the public. (…) Implementation needs to ensure all staff are fully trained and supported to help families through the process."[297]

436. A number of stakeholders were worried about the additional burdens introducing a soft opt-out system would have on medical practitioners and whether they would be adequately trained to understand and deal with the change in the law.

437. Dr Dariusz Tetla stated in written evidence:

> "It's commonly known and accepted that organ donation is a particularly difficult area of clinical practice. While introducing 'soft' opt-out system may result in increased number of transplantations, it will certainly impose additional burden on medical practitioners."[298]

438. The RCN voiced similar concerns:

> "If a new system were to come into operation in Wales, a pressing concern of the Royal College of Nursing would be the need for training and education for nursing staff. Nurses and health care support workers are the largest staff group in the NHS and the most likely to be in direct daily contact with patients and families. Specific resources must be developed and targeted at this group."[299]

439. The Royal College of General Practitioners also referred to the burden of the additional workload arising from the proposals:

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[296] RoP, pararaph 591, 24 January 2013, Health and Social Care Committee
[297] Written evidence, HT(Org)4
[298] Written evidence, HT(Org)14
[299] Written evidence, HT(Org)15

> "Although General Practitioners on the whole would be supportive of the improvement in the numbers of donor organs for the benefit of those in need, we do not feel that they can be expected to counsel patients about opting out or in of donations. (…)"
>
> "There were suggestions that this process would occur at registration at the GP. However, as we are sure you are aware, the work load of general practice has increased considerably over the past few years and additional work outwith general medical service provision would be difficult to contemplate. There would likely be considerable burdens on ensuring that the details of individuals were recorded accurately at the time of registration and for individuals to be made aware and to be informed about consent as well as training requirements for practice staff to ensure they were competent to take such consent."[300]

440. Mr Phil Walton emphasised the impact of effective training:

> "The SNOD consent rate is classed as the SNOD-collaborative-approach rate, which means that if a SNOD is present in a room with a clinician, the success rate is around 70% to 75%. If it is a consultant-only approach it is around 50%. (…) part of our training allows us to provide clarity and detailed information about the entire process. It is done in a format that means you get the same information regardless of whichever SNOD approaches that family. We do not have control over what information a clinician would give to the family, so there would be variants."[301]

Evidence from the Minister

441. In relation to training for specialist nurses and clinical leads for organ donation, the Minister's policy official told us:

> "We are working with [NHSBT] on this particular work to define and agree on what training and awareness may be needed. That is, in terms of how the registration will work and

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[300] Written evidence, HT(Org)22

[301] RoP, paragraph 262, 20 February 2013, Health and Social Care Committee

> conversations with family. So, we are already having those conversations with it now. In the overall cost provision, we have made available funding for training."[302]

442. Further to this, the Minister told us:

> "The type of questions asked of families, even today, may seem intrusive and unnecessary to those of us not involved in the organ donation process. However, the skill and training of the Specialist Nurses means they are approached sensitively and with care. I believe the requirements of the new system can be carefully woven into the conversation and will not cause significant difficulties for staff or families."[303]

Our view

443. We recognise the important role that health professionals play in promoting organ donation and guiding families through the organ donation process.

444. We also recognise that health professionals involved in the new system will need to be adequately trained in order to deliver maximum benefits. This training will need to be flexible in order to meet the needs of medical professionals with different levels of involvement in the process.

445. In terms of the positive impact of specialist training, we were particularly interested in the evidence from Mr Phil Walton on the SNOD-collaborative approach consent rate, as this demonstrates the importance of families being approached by well-trained SNODs, in collaboration with clinicians.

446. As such, we believe the Minister should satisfy himself that sufficient funding and resources are in place to ensure that effective training is provided for medical professionals in relation to any new system of deemed consent. Further to this, we recommend the Minister provide confirmation of this in a revised Explanatory Memorandum following stage 2 proceedings.

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[302] RoP, paragraph 433, 24 January 2013, Health and Social Care Committee

[303] Letter from the Minister for Health and Social Services, 14 February 2013

447. Finally, we acknowledge that there will be a need to provide training for medical staff in other parts of the UK to ensure they are aware of any new system in Wales. The Minister must ensure that appropriate arrangements are made for this.

9. Financial Implications of the Bill

Background

448. A Regulatory Impact Assessment (RIA) is provided at Part 2 of the Explanatory Memorandum and includes a cost-benefit assessment of the options for delivering the Bill's policy objectives.

449. The RIA states that patients who receive transplants on average benefit from extended life and an improvement in quality of life valued at £60,000 per additional year of perfect health (Quality Adjusted Life Years (QALYs) where a year of perfect health is worth one QALY valued at £60,000).[304]

450. The RIA notes that there will be fixed set-up costs (business and system changes; the cost of processing opt-out requests; public communications and evaluation) required to operate a soft opt-out system of organ donation. The RIA estimates the costs (discounted over 10 years at 3.5 per cent) to be approximately £8 million, which will be borne by the Welsh Government. Of this, almost 40 per cent (£2.9 million) relates to communications and just over 30 per cent (£2.5 million) to IT changes.[305]

Evidence from consultees

451. The majority of witnesses who commented on the financial implications of the Bill voiced concerns about the budget set aside for this and the associated communications campaign, and the information used to develop the cost-benefit assessments.

452. In general terms, both the Kidney Wales Foundation and the British Heart Foundation Cymru stated they believed the Bill and a system of deemed consent would provide value for money.[306]

453. In oral evidence, Sally Johnson of NHSBT commented on the discussion that had been held between NHSBT and the Welsh Government regarding the cost of developing and implementing an organ donation register to accompany any new deemed consent system. She said:

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[304] EM, page 39, paragraph 115

[305] EM, page 38, paragraph 111, and EM, page 45, RIA Appendix 1

[306] RoP, paragraph 504, 24 January 2013, and Written evidence, HT(Org)21

> "The costs that are in the Bill are those that we have been discussing with the Welsh Government. (…) we have worked together and engaged some external people who have experience in developing such registers to tell us what they think that it would cost. We have had that quality-assured by a separate company… The costs are estimated to the best of all the experts' abilities, but it will have to go out to tender. (…) we will have to see what the tenders come back at. That is a standard NHS procurement process."[307]

454. The evidence from Professor Ceri Phillips focussed on three main issues: the lack of research base for the cost effectiveness of donation/transplantation or organs other than kidneys; the Welsh Government's QALY estimate for donation; and the relationship between the Welsh NHS and the UK-wide NHS in terms of where the cost-benefits would be realised.[308]

455. On the subject of Local Health Boards (LHBs) realising savings, Professor Phillips stated that the research base for kidney savings from the cost of transplant offset by the cost of treatment was "pretty conclusive". However for some of the other areas of transplantation, he said there was less evidence and therefore the assumptions made in the RIA "need to be challenged, perhaps":[309]

> "The number of organs that will materialise from additional donors is (…) based on assumptions. If you look closely at that, the ongoing treatment costs from the transplant will be greater than any treatment savings in the case of liver transplants, heart transplants, and lung transplants. It is only in kidney transplants, where the cost of dialysis is saved, that the costs are reduced by the offsetting of benefits. The analysis is based to a large extent on the value put on those health gains."[310]

456. Professor Phillips went on to say that he believed the policy had the potential to deliver value for money "but what we do not have information on is the relative value for money compared with

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[307] RoP, paragraph 573, 24 January 2013, Health and Social Care Committee
[308] Written evidence, HT(Org)10
[309] RoP, paragraph 349, 30 January 2013, Health and Social Care Committee
[310] RoP, paragraph 341, 30 January 2013, Health and Social Care Committee

increasing communication and getting more people aware of the benefits of opting in, as opposed to opting out."[311]

457. The second main issue raised by Professor Phillips was that of the Welsh Government's QALY value of £60,000.[312] In oral evidence, Professor Phillips explained his concerns:

> "(…) when you look at the way in which the benefit stream has come through in the appraisal, a lot of the emphasis is on what they call the gains in quality adjusted life years, which the economists in Welsh Government have derived from Department of Health estimates. They have used a base figure value of £60,000 per QALY. I have slight concerns about that, because the National Institute for Health and Clinical Excellence, when it does appraisals of new therapies, usually approves therapies that come in at £20,000 per quality adjusted life year—£60,000 seems high."[313]

458. He said that "even when you consider that, when we are talking about end-of-life therapies, NICE may allow for a slightly higher QALY value, it is not usually at the £60,000 estimate."[314]

459. Professor Phillips said he believed that six additional donors would represent a "break-even point, and probably eight donors would give you value for money." He acknowledged that the Minister's intention was to gain an additional fifteen donors under the Bill and that this would produce a cost benefit, but suggested that the Minister's assertion that one additional donor would be enough to break even "would not necessarily be as efficient as perhaps the estimate within the assessment suggest."[315]

460. In their evidence, Cardiff and Vale University Health Board Organ Donation Committee also questioned the QALY assessment and called for clarification on the figures provided in the RIA.[316]

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[311] RoP, paragraph 342, 30 January 2013, Health and Social Care Committee
[312] Written evidence, HT(Org)10
[313] RoP, paragraph 340, 30 January 2013, Health and Social Care Committee
[314] Ibid.
[315] RoP, paragraphs 242, and 355-359, 30 January 2013,
[316] Written evidence, HT(Org)12

461. In contrast, Roy Thomas of the Kidney Wales Foundation stated that he believed the cost estimates set out in the RIA, particularly those related to the QALY, were “clear”.[317]

462. The third issue raised by Professor Phillips related to where, and by whom, the cost-benefit of a deemed consent system would be realised, in monetary terms.[318]

463. Professor Phillips suggested that the Welsh Government’s cost benefit analysis did not take into account that, in many cases, the cost of retrieving a kidney would fall on NHS Wales but that there was a high possibility that the person in receipt of the donated kidney would be located outside Wales. As such, the compensating savings in terms of dialysis would not be savings realised by NHS Wales.[319]

464. This point was also raised by the Clinical Ethics Committee of Abertawe Bro Morgannwg:

> “The likely small proportion of donated organs that will be transplanted into residents of the same LHB area, or of Wales, means that savings from the post-transplantation reduction in medical care (such as dialysis) will not be released locally.”[320]

465. The financial impact on critical care provision and LHB resources was another issue raised by some consultees.

466. The Organ Donation Committee of the Cardiff and Vale LHB stated the increase in donor numbers estimated at 15 per year will have an impact on resources, especially in critical care, and that the workload on the critical care departments cannot be calculated by looking at donors alone.[321]

467. This view was echoed by the Clinical Ethics Committee of Abertawe Bro Morgannwg University Health Board which stated that it has significant concerns about the need for a shift of resources to

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[317] RoP, paragraph 504, 24 January 2013, Health and Social Care Committee

[318] Written evidence, HT(Org)10

[319] RoP, paragraph 361, 30 January 2013, Health and Social Care Committee, and Written evidence, HT(Org)10

[320] Written evidence, HT(Org)26

[321] Written evidence, HT(Org)12

provide the additional theatre and critical care capacity required to deliver an increase in transplantation rates.[322]

Evidence from the Minister

468. The Explanatory Memorandum states that the costs associated with obtaining consent, organ retrieval and transplantation will be borne, in part, by the NHS in Wales, within existing LHB budgets and resources and within the Welsh Government NHSBT grant.[323] The Explanatory Memorandum further states that the Minister does not believe that an increase in donor rates as a result of this Bill would incur additional costs on critical care and surgical services.[324]

469. In relation to the estimated QALY value, the Minister told us that she had commissioned a "very thorough financial impact assessment" of the Bill and, therefore, whilst noting the evidence from other witnesses, she did not accept that she had "over-valued the QALY".[325]

470. On this point, the Minister's policy official told us:

> "In this particular case, it was our economists picking up on advice from the Department of Health. (…) I add to that that the sensitivity analysis, which is in the explanatory memorandum, says that even if you allow for the QALY to be the lower one that you are talking about, there is still an overall cost benefit to a relatively low number of extra donors."[326]

471. In relation to where the cost-benefits would be realised, the Minister's policy official told us that the RIA contained an assessment of the percentage of organs that will be retained in Wales and the potential cost savings to the Welsh NHS and Welsh budget as compared with Scotland or England. He said:

> "(…) if you allowed for, broadly, a 30% retention of organs in Wales, which reflects the last four years, then essentially, (…) one extra donation would pay for the system."[327]

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[322] Written evidence, HT(Org)26
[323] EM, page 38, paragraphs 111-112
[324] EM, page 42, paragraph 134
[325] RoP, paragraph 163, 20 February 2013, Health and Social Care Committee
[326] RoP, paragraph 165, 20 February 2013, Health and Social Care Committee
[327] RoP, paragraph 451, 24 January 2013, Health and Social Care Committee

472. Further to this, the Minister told us:

> "The cross border nature of the transplantation programme means it is not always a simple matter to directly attribute costs and savings to particular organisations – there is nothing particularly new in that – however the NHS in the UK and society as a whole benefits. I do not dismiss the point being made, but I feel these are relatively minor considerations in the overall scheme of things, and can detract from the wider aim of the legislation."[328]

473. We asked the Minister about the potential financial impact on critical care provision and the need for LHBs to meet the running costs associated with an increase in organ donation rates. Responding to this, she said that, whilst the LHBs would be spending money in some areas, they would be saving money in others; for example, costs saved through a reduction in dialysis. As such, she said she expected the LHBs to balance their budgets."[329]

474. The Minister did, however, go on to say that this issue "could be reviewed in the future".[330]

Our view

475. We note the Minister's view that an increase in donor rates under the Bill would not incur additional costs for critical care and surgical services. In light of the evidence we have received, we are not convinced on this point and believe it would merit further consideration. We welcome the indication from the Minister that this is a matter that could be reviewed in the future but, as referred to in paragraph 145, we recommend the Minister prepare and publish a detailed plan of the resource implications of the Bill for the future of critical care capacity in Wales, and that he does so before the end of Stage 2 proceedings.

476. We note the evidence base for cost-benefits in relation to transplants is mainly in respect of kidneys, rather than other organs. However, in view of the evidence on this matter, we are satisfied that,

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[328] Letter from the Minister for Health and Social Services,28 February 2013
[329] RoP, paragraph 446, 24 January 2013, Health and Social Care Committee
[330] Ibid.

overall, the policy objective in the Bill has the potential to deliver value for money.

477. We note that some queries have been raised with us in terms of the Minister's QALY estimate. We draw this evidence to the Minister's attention.

478. In addition to this, we have expressed a view on the financial implications in relation to other aspects of the Bill. These views are set out in Chapters 4, 7 and 8.

479. Finally, we wish to highlight the evidence that, while the costs of the new system will be borne by the NHS in Wales, most of the likely benefits will be accrued by the UK NHS.

10. Other issues

480. In addition to those matters discussed in previous chapters, there are a number of more specific issues that were raised with us by respondents. The purpose of this chapter is to address these issues, as follows:

- terminology;
- DBD and DCD;
- novel forms of transplantation;
- organs for research purposes; and
- the application of the Bill to living persons.

Terminology

481. We heard a variety of views about the use of the word "deemed" in the Bill in relation to consent. It was noted that, in the Welsh Government's White Paper[331] on organ donation, the term "presumed" was originally used. However, for the purposes of the Bill, this has been changed to "deemed".

482. Some respondents also commented on other terminology in the Bill.

Evidence from consultees

483. In oral evidence, Professor Harpwood, Chair of the Cwm Taf Organ Donation Committee, stated:

> "I understand how the word 'deemed' got into this Bill, because it is in the Human Tissue Act 2004, so it has a history, as it were. However, its use often leaves important details to be worked out by the reader—I mean, there is not a lot of clarity about what 'deemed' means, and there are many different sorts of 'deeming' in legal terms. So, why not use the word 'presumed'? Everybody understands that. Why not be clear, up front, as to what we really mean, because that is what it is?"[332]

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[331] Proposal for Legislation on organ and tissue donation: A Welsh Government White Paper

[332] RoP, paragraph 134, 30 January 2013, Health and Social Care Committee

484. Dr Dariusz Tetla believed:

> "The history of the use of deemed indicates that it can be a complex and difficult word even for lawyers. In my view there is a strong case for grasping the opportunity that we have now in Wales to produce clear legislation which can readily be understood by the majority of the population."[333]

485. However, in his evidence, Professor John Saunders stated that the concept of presumed consent was "as nonsensical as talking about a square circle" and that it had "mercifully, been expunged" in the latest version of the Bill. He said it was essential that consent represented the autonomous choice of the individual and therefore it could not be presumed.[334]

486. The Kidney Wales Foundation were also supportive of the term "deemed consent", saying that "it provides clarification and is preferable to presumed consent which can often be misinterpreted."[335]

487. A number of stakeholders raised the point that many countries that operated a similar soft opt-out system used the term "presumed" or "opt out", rather than deemed. On this point, the Human Tissue Authority said that the use of the term "'deemed' or even 'presumed' suggests something that is fairly passive, and consent is an active process".[336]

488. Dr Tetla told us that he thought "it would be helpful if the expressions DCD and DBD were defined in the Bill."[337]

489. Some stakeholders, including the South Wales Jewish Representative Council[338], told us they were concerned that "death" and "deceased" were not defined in the Bill.

490. Professor Harpwood stated:

> "Those sorts of cases are really referring to donation after brain death as opposed to donation after cardiac death, but nowhere

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[333] Written evidence, HT(Org)14A
[334] RoP, paragraph 272, 7 February 2013, Health and Social Care Committee
[335] Written evidence, HT(Org)25
[336] RoP, paragraph 176, 30 January 2013, Health and Social Care Committee
[337] Written evidence, HT(Org)14A
[338] Written evidence, HT(Org)9

> is there a definition or an explanation of what this really means to ordinary people. Ask an ordinary person on the street what they understand by 'dead'; what is the definition of death? It is a very difficult area and I do not know how it can be approached. It would need to be done very sensitively."[339]

491. She goes on to state

> I would like to see the Bill containing something by way of definition. In Wales, we have tabula rasa. (…) We should be upfront, clear and make our legislation accessible. If that involves including a definition of death and something that refers to DBD and DCD, I think that we should go down that route.[340]

492. Professor Harpwood and NHSBT believed that, to avoid confusion, the word "deceased" should be removed from section 12 of the Bill.[341]

Evidence from the Minister

493. In relation to a definition of "death" or "deceased", the Minister said:

> "The Bill deals with consent to donation and does not alter any current practice in terms of the diagnosis of death. I am aware of Professor Harpwood's evidence to the Committee but, with respect, I do not agree that we should define these terms in the legislation. There is no current statutory definition of death/deceased person, but rather a duty exists in the Human Tissue Act 2004 and as amended by our Bill to empower the HTA to issue guidance on the matter. (…) Whilst I appreciate Professor Harpwood's view that we could start with a clean slate in Wales and choose to define these matters, I do not think this is something which we should be seeking to include in our legislation."[342]

494. She continued:

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[339] RoP, paragraph 86, 30 January 2013, Health and Social Care Committee

[340] RoP, paragraph 94, 30 January 2013, Health and Social Care Committee

[341] RoP, paragraph 84, 30 January 2013 and RoP, paragraphs 554-557, 24 January 2013, Health and Social Care Committee

[342] Letter from the Minister for Health and Social Services, 14 February 2013

> "However, in light of both Professor Harpwood and Sally Johnson's comments, officials are reviewing the use of the word "deceased" in section 12 of the Bill in the context of taking steps for preservation for transplantation."[343]

Our view

495. We recognise that some witnesses favour the use of the word "deemed", while others favour "presumed".

496. Members of the Committee have different views on which term is preferable, but all are agreed that, when it comes to explaining the new system for consent, the language and terminology used should be clear and easy to understand.

497. In relation to section 12 of the Bill (preservation of organs for transplantation) and a definition of "death" or "deceased", we welcome the Minister's commitment to give further consideration to the use of the word "deceased".

Donation after brain death (DBD) / Donation after circulatory death (DCD)

Evidence from consultees

498. Several respondents, including the UKDEC and the Anscombe Bioethics Centre, drew attention to the difficulties in establishing whether additional interventions in the last hours of a patient's life for the purposes of DCD would be in that patient's best interests.

499. On this point, the UKDEC told us that:

> "A particular issue arises in the context of donation after circulatory death (DCD), which accounts for nearly 40% of solid organ donations. The decision-making about donation for a DCD donor happens while the donor is still alive, but lacking capacity. Such decisions are therefore covered by the Mental Capacity Act, and in order for donation to proceed it has to be established that activities to facilitate donation are in the patient's best interests."[344]

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[343] Letter from the Minister for Health and Social Services, 14 February 2013

[344] Written evidence, HT(Org)4

500. They said it was important, on both a practical and legislative level for the Bill to be "clear on the consent status of a potential DCD donor who may not have opted out, but is still alive and lacking capacity at the time of decision-making about donation". [345]

501. The UKDEC continued:

> "The inevitable upward trend in the demand for organs for transplantation means that clinical practice in transplantation needs to constantly evolve and find new and better ways of delivering successful donations. Donation after circulatory death (DCD) is an important potential source of increasing the organs available for transplantation, particularly hearts. (…) decisions about DCD donations need to be made whilst the potential donor is still alive. These decisions can be ethically challenging, since there are a range of interventions that might be carried out on a dying patient that will optimise the condition of organs, but have no benefit to the patient other than fulfilling his or her wish to be a donor. Therefore the justification for intervening, and the balance of benefits and burdens that need to be weighed up in deciding whether an intervention is in the patient's best interests, relies heavily on the strength of evidence that the patient wants to be an organ donor."[346]

502. The Clinical Ethics Committee, Abertawe Bro Morgannwg University Health Board made a similar point, saying:

> "In the case of DCD the person may in life have non-therapeutic interventions, so as to facilitate organ retrieval after they die, that would otherwise have been contrary to their best interests."[347]

503. They went on:

> "(…) we therefore strongly suggest either that DCD is excluded from these proposals entirely or at the very least that any additional intervention in life intended to facilitate retrieval

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[345] Written evidence, HT(Org)4

[346] Ibid.

[347] Written evidence, HT(Org)26

> after death that in the reasonable judgment of the clinical team has any potential to cause distress is specifically prohibited without express consent."[348]

Evidence from the Minister

504. In correspondence, the Minister provided an explanation of the terms 'DBD' and 'DCD' and how the Bill applies in relation to them.[349]

505. She went on to say:

> "In either DBD or DCD, it is important to separate decisions about the care and treatment of the patient from decisions about organ donation (…). The provision in the Bill and the introduction of a system of deemed consent do not alter this in any way. The Bill, as in the current Human Tissue Act, makes it lawful to take steps to preserve part of a body for potential transplantation, including in those situations where it is still being established if a decision on consent has been or will be made."[350]

506. She continued:

> "Having a system of deemed consent does not somehow make it "easier" to retrieve organs or exert undue influence over decisions around the care and treatment of a patient. It merely indicates the deceased individual may have had no objection to the idea of organ donation and informs the conversation with family members which may then ensue."[351]

507. The Minister's policy official said he was not aware of any baseline measurements that had been undertaken to assess people's understanding of DCD and DBD.[352]

Our view

508. We believe that most people's understanding of death is something akin to DBD; so they will assume this for the purposes of

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[348] Written evidence, HT(Org)26

[349] Letter from the Minister for Health and Social Services, 14 February 2013

[350] Ibid.

[351] Ibid.

[352] RoP, paragraphs 37-38, 20 February 2013, Health and Social Care Committee

deemed consent. It is unlikely that there will be a common understanding of DCD, so we asked ourselves whether it was reasonable to deem consent in these cases.

509. The majority of us were satisfied with this, provided the safeguards already in place in relation to DCD are fully maintained. Those Members who did not support the principle of deemed consent regarded its application as especially objectionable in the case of DCD.

510. It is also important that, in this rapidly developing area of medicine, the particular ethical issues that arise in relation to DCD are kept regularly under review. Steps must be taken to ensure that families are properly advised of the particular issues around this when discussing the matter of consent to donation.

Novel forms of transplantation

511. Section 16 of the Bill defines "relevant material" from a human body that can be used for the purposes of transplantation. It states that "relevant material" means material, other than gametes, which consists of or includes human cells.

Evidence from consultees

512. A number of respondents questioned whether the Bill would include novel forms of transplantation, such as face or limb transplants. On this point, the HTA said:

> "At present the Welsh Government's plans in regard to deemed consent only address solid organs. However, the Bill provides scope for the transplantation of any relevant material to be lawful with deemed consent. This means that there would be no need for the legislative process to be undertaken to introduce deemed consent to the transplantation of other relevant material."[353]

513. The BTS said that they thought that deemed consent under the Bill could include "the more unusual and emotive forms of transplantation such as hand/arm and face transplants."[354]

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[353] Written evidence, HT(Org)27

[354] Written evidence, HT(Org)7

514. The BMA Cymru Wales also referred to novel forms of transplantation, such as face or limb transplants, saying:

> "In the BMA's view express consent should continue to be required for such procedures for the foreseeable future, and a Regulation making power should be included in the Bill to exclude such forms of donation."[355]

515. The Society for the Protection of Unborn Children also referred to the issue of face and limb transplants, as well as "other transplant techniques [which] may permit gonadal tissue to be transplanted, leading to the potential for children to be born whose biological parents are deceased."[356]

516. In their view:

> "(…) as far as the issue of consent is concerned, ethically more contentious transplantation would become more rather than less problematic under a presumed consent system."[357]

517. Professor John Saunders felt that requiring the Minister to set out in regulations where and how human body parts or relevant material from human bodies may or may not be used would provide clarity, while ensuring there was enough flexibility to adapt to changing circumstances over time.[358]

Evidence from the Minister

518. The Minister stated that, in relation to novel forms of transplantation (i.e. composite tissue transplants), the current practice is that the express consent of family members is required, even if the deceased person is on the ODR, and that this would not change under the Bill.

519. However, she stated that she understood the concerns that had been raised and was:

> "(…) prepared to bring forward a Government amendment to include a specific power of Direction for the Welsh Ministers.

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[355] Written evidence, HT(Org)18

[356] Written evidence, HT(Org)20

[357] Ibid.

[358] RoP, paragraph 327, 7 February 2013, Health and Social Care Committee

> The power will mean Welsh Ministers, after consultation, can give directions to NHS Blood and Transplant on which organs and tissues will not be included in the deemed consent system. My intention will be to exclude from the deemed consent arrangements so-called "composite tissue" donations such as face and limb."[359]

Our view

520. In relation to arrangements for consent for composite tissue transplants, we are content with the Minister's response that the Bill will not change the current requirement for express consent.

521. However, we believe the Minister should provide more detail about the organs to be excluded for the purposes of deemed consent.

522. We welcome the Minister's intention to include a power of direction for Welsh Ministers on the face of the Bill in relation to composite tissue donation. However, we recommend that a list of organs to be excluded from deemed consent should be defined in regulations. Such regulations should be subject to consultation and Assembly oversight via the affirmative resolution procedure.

Research

Evidence from consultees

523. The use of organs for research purposes is currently permitted under the Human Tissue Act 2004. The question of whether the Bill should include provision for research was raised with the Committee.

524. The UKDEC stated that the use of organs for research was necessary in order to improve the donation process:

> "We must consider the normal processes that go on. Research can mean a whole range of things. In other words, research will be done on perfusing donated lungs in order to improve their function, and then a recipient will be told that the lung has had that treatment and asked if they are happy to receive it. In

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[359] Letter from the Minister for Health and Social Services, 28 February 2013

> other words, research is going on with donated organs at the present time."[360]

525. They continued:

> "Research also takes place in organs that are deemed unsuitable for transplantation. Research is necessary, particularly, as I have highlighted, in the areas of trying to improve organ function by chemical means or whatever. So, if we are not going to have the opportunity in a patient who is deemed to have consented for their organs to be used for research or included in a research project, if not suitable for immediate transplantation, it adds another dimension to the problem. It means that there is only a fairly unique area in which the organs can be used. Therefore, I think that the Bill ought to take account of research."[361]

526. The Nuffield Council on Bioethics said that donation of material for research purposes should be routinely raised with the families of the deceased when authorisation for the removal and use of organs or tissue is sought.[362]

Evidence from the Minister

527. The Minister confirmed that the use of organs and tissues for research purposes will not be covered by the Bill.[363]

Our view

528. We acknowledge the evidence that, as a result of the Bill not making provision for organs donated under a deemed consent system to be used for research purposes, there is a risk that fewer organs may be available for those purposes. We wish to draw this to the Minister's attention.

529. We recommend that the communications programme to accompany the Bill should include information about the use of organs for research and should inform people that they need expressly to opt in to the ODR if they wish their organs to be available for research.

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[360] RoP, paragraph 315, 30 January 2013, Health and Social Care Committee

[361] RoP, paragraph 315, 30 January 2013, Health and Social Care Committee

[362] Written evidence, HT(Org)8

[363] RoP, paragraph 333, 24 January 2013, Health and Social Care Committee

The application of the Bill to living persons

530. Section 8 of the Bill deals with activities involving material from living adults who lack capacity to consent.

Evidence from consultees

531. NHSBT queried some of the wording within the Bill and were worried that the inclusion of blood, blood products, blood components and stem cells and the section on living donation within the Bill would cause confusion and distract from its main purpose of organ and tissue donation.

532. They stated:

> "While the primary focus of this bill is to introduce a system of deemed consent in Wales we are worried that including references to living donation could lead to misunderstanding. We would favour references to living donation being removed from the bill and the Human Tissue Act 2004 remain the legal basis of living donation in Wales."[364]

533. They went on:

> "Section 17(6) states that references to transplantation shall include transfusion. While this is identical to Section 54(3) of the Human Tissue Act 2004 we believe that the reference to transfusion in the 2004 act was intended to ensure that blood products, transplantation and transfusion are included in the criminal offence of commercial dealings in Section 32 of the Act, as section 15(5) of the act specifically excludes blood and blood products from the regulatory remit of the Human Tissue Authority. As the Human Transplantation (Wales) Bill does not address the criminal offence of commercial dealings, we believe that for the sake of clarity it is important to add; blood, blood products, blood components and stem cells to the list of exceptions contained in Section 16(2) of the bill."[365]

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[364] Written evidence, HT(Org)5

[365] Ibid.

Our view

534. We believe there is merit in the views raised by the NHS Blood and Transplant that, to avoid confusion, the Bill should not make provision in respect of living donors and we recommend that the Human Tissue Act 2004 should remain the legal basis for such donations.

11. Code of Practice

Background

535. Section 14 of the Bill makes provision in relation to codes of practice.

Evidence from consultees

536. In relation to codes of practice, the HTA confirmed that, once enacted, the Bill will place a number of duties on it, one of which will be to produce a revised code of practice. The HTA will also be under a "duty to superintend" the Act, which will include providing advice and guidance on how the legislation should be interpreted.[366]

537. The HTA told us that it had been formally invited by the Welsh Government to start work on a new code of practice and that a joint working group that will develop the new code had already begun its work.[367]

538. Further to this, it stated:

> "While the HTA has not yet had the opportunity to undertake a full analysis of the impact of the Bill, an initial assessment has identified a number of possible risks to the implementation of the provisions from a regulatory perspective. These relate to our role in advising on the practical circumstances under which consent can be deemed."[368]

539. It added:

> "(…) the consequences of failing to identify an express wish not to donate under a system of deemed consent (and the donation proceeding) seem to be of a different magnitude ethically and legally. As a result we would expect to take a range of stakeholder views on the appropriate checks to undertake in order to reflect these in a Code of Practice. While our experience (in partnership with NHS Blood and Transplant) will allow us to develop a Code of Practice, a system so designed

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[366] Written evidence, HT(Org)27

[367] RoP, paragraph 203, 30 January 2013, Health and Social Care Committee

[368] Written evidence, HT(Org)27

> may pose a number of operational challenges. We are working with officials in Wales and colleagues in NHSBT to address these issues."[369]

540. The HTA stated that they envisaged the development of a new code of practice would take approximately 15 to 18 months, and that a draft code of practice should be developed by the end of this year.[370]

541. In response to the question as to why the new code would not be available sooner, the HTA said:

> "There is potentially a chicken-and-egg situation here, which is that in order to start developing a code of practice, we need sufficient detail in a virtually finalised Bill from which to start working, and then we need to engage with people who are going to be doing that operation or the delivery of it."[371]

542. We also heard evidence in relation to the code from Patient Concern, who said that the code needed to be "very strong", especially regarding the role of the family.[372]

Evidence from the Minister

543. The Explanatory Memorandum states that guidance relating to the provisions of the Bill will be set out in the codes of practice prepared by the responsible authority, currently the Human Tissue Authority (HTA) and that these codes will be approved by Welsh Ministers and laid before the Assembly.[373] As drafted, the Bill makes provision for the negative resolution procedure for the agreement of a code.

544. Given the importance of the Code, we asked the Minister whether it would be possible to have sight of the draft code in advance of the Bill reaching its final scrutiny stage.

545. In response to this, she told us:

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[369] Written evidence, HT(Org)27

[370] RoP, paragraph 203, 30 January 2013, Health and Social Care Committee

[371] RoP, paragraph 207, 30 January 2013, Health and Social Care Committee

[372] RoP, paragraph 52, 7 February 2013, Health and Social Care Committee

[373] EM, page 22, paragraph 55

> “My officials are in discussion with the Human Tissue Authority about the drafting of the Code and its contents, including whether there should be any further reference to diagnosis of death and DCD cases; the issues raised about nominated representatives and what should happen when there is more than one [nominated representative] and they do not agree.” [374]

546. She confirmed:

> “(…) it is my intention the Committee will be provided with a draft code before Stage 3.”[375]

Our view

547. We note the evidence received in relation to the development of codes of practice to accompany the Bill.

548. We note the role of the HTA in preparing these codes and we welcome its stated intention of consulting with stakeholders as part of this.

549. Given the importance of the Code in providing guidance on the provisions and implementation of the Bill, we welcome the Minister’s commitment to provide us with sight of the draft Code of Practice in advance of Stage 3 proceedings. We expect to receive this before the end of Stage 2 proceedings in order for us to be able to consider it fully in preparation for Stage 3. Further to this, we recommend that, when the Minister shares the draft Code with us, he also makes it publicly available.

550. Finally, we note that the Bill, as currently drafted, provides for the Code of Practice to be laid before the Assembly (we welcome this) and be subject to the negative resolution procedure. Again, given the significance of the Code, we recommend that, once laid, it should be subject to the affirmative resolution procedure.

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[374] Letter from the Minister for Health and Social Services, 28 February 2013

[375] Ibid.

12. Evaluation of the Act

Background

551. The Explanatory Memorandum states:

> "The Welsh Government is committed to monitoring and evaluating the effect of the introduction of this legislation."[376]

552. It goes on to state that the Welsh Government will commission a scoping project in 2012-13 to establish baselines, followed by an independent evaluation beginning in 2013-14 which will monitor donor statistics, public attitudes and undertake qualitative research with NHS staff involved with donation before and after implementation of the legislation.[377]

Evidence from consultees

553. During the Committee's scrutiny of the Bill, a number of witnesses commented on the need to evaluate the success of the Bill, if enacted, and its principal objective of increasing organ donation rates in Wales.

554. In his written evidence, Professor John Saunders said that, if it implemented this Bill, Wales would be a "pilot project for the rest of the UK":

> "If it can be clearly demonstrated that the Bill really has made a difference, then England and Scotland and Northern Ireland will follow suit, to the great benefit of thousands of patients. If the numbers transplanted falls then the reverse applies. It is therefore critical that what constitutes success is set out in advance and not the subject of argument afterwards." [378]

555. He continued:

> "The risk is that if donation continues to rise at the same rate as it is currently rising, there will be a political incentive to now

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[376] EM, page 57, RIA Appendix 5
[377] Ibid.
[378] Written evidence, HT(Org)28

> claim that it results from the Bill, when it would have happened anyway." [379]

556. As part of his oral evidence, Professor Saunders provided some suggestions as to how any such evaluation could be undertaken:

> "(…) transplantation performance is improving in Wales at the moment, and indeed through the UK. So, you have an upward line. We can then start projecting from where we are at the moment how much we have improved matters after three years, five years, 10 years, or whatever it happens to be... We can extrapolate forward, and we can therefore make some sort of prediction… as to where we would expect to be in three years, five years, or whatever. We can then say mathematically what would be a statistically significant difference from that line upwards or downwards (…)."[380]

557. He went on:

> "Allowing for the wobble that there is in all human systems, we could go for what in the [explanatory] memorandum … is called 'predicting counterfactuals', so you have a prediction of where you would be with this and what would count as success—and of course what would count as failure."[381]

558. In commenting on the issue of an evaluation strategy, the HTA advised that review periods should be built into the post-implementation programme in order to assess the impact of the legislation. The HTA added:

> "If the impact is a drop in the number of organs being donated, steps should be taken rapidly to understand the root causes. Negative coverage of deemed consent in Wales could lead to mistrust in other parts of the UK, and it will be vital that this change does not adversely impact organ donation."[382]

559. The HTA went on to note that both the Scottish Government and Northern Ireland Assembly have expressed interest in the Welsh

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[379] Written evidence, HT(Org)28
[380] RoP, paragraph 330, 7 February 2013, Health and Social Care Committee
[381] Ibid.
[382] Written evidence, HT(Org)27

Government's proposals and, as such, the "unique opportunity" to share the experience should not be lost as any post-implementation review may form the basis of policy decisions in other parts of the UK.[383]

560. The BTS offered similar views to those expressed by the HTA and added:

> "It would be tempting for the government to audit the process itself, but it might be better received externally were some independent assessment be included in the process and we would like to encourage this."[384]

561. The Nuffield Council on Bioethics also stressed the importance of any new opt-out system being accompanied by:

> "(…) robust research, both on the role of relatives in determining whether organs may be donated, and on the effect that the legislative change (as opposed to any confounding factors such as system changes) has had on the numbers of organs donated. Such research would provide a clear evidence base for any proposals for change elsewhere in the UK, or indeed further afield."[385]

Evidence from the Minister

562. In her evidence, the Minister told us that a "very robust evaluation strategy was needed to monitor the legislation".[386]

563. She went on:

> "We need to look at the evidence from other countries to determine the impact of the Bill, and the monitoring of donor rates and family consent rates now, and after the introduction of the Bill, [this] would give us a very good indication of the success of the legislation and the impact of the Bill."[387]

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[383] Written evidence, HT(Org)27
[384] Written evidence, HT(Org)7
[385] Written evidence, HT(Org)8
[386] RoP, paragraph 157, 20 February 2013, Health and Social Care Committee
[387] Ibid.

564. The Minister later confirmed that her officials were working on the draft evaluation strategy, and that she would share this with Members "within the next month or two".[388]

Our view

565. In relation to evaluating the impact of the Act on organ donor rates, we agree with witnesses that any move to a deemed consent system in Wales is likely to be the subject of considerable interest in other parts of the UK and further afield.

566. We recommend that any such change in the legislative arrangements for consent should be accompanied by a robust evaluation strategy, which would provide both the means of measuring the success of such a change and a clear evidence base for policy decisions elsewhere.

567. In order to achieve this, however, we recommend the Minister declare, in advance of the Bill concluding its passage through the Assembly, what he considers will be the measures of its success and the timescales for any assessments of this.

568. In that context, we note that the Minister is in the process of preparing a draft evaluation strategy, and we welcome the commitment to share it with us shortly.

569. Some members of the Committee were of the view that the implementation of the Bill should be subject to an independent evaluation in due course.

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[388] RoP, paragraphs 160-161, 20 February 2013, Health and Social Care Committee and Letter from the Minister for Health and Social Services, 28 February 2013

Annexe A: Written evidence

570. We received a large number of written responses to our consultation. Those that we have had authorisation to publish can be viewed in full at:

http://www.senedd.assemblywales.org/mgIssueHistoryHome.aspx?IId=5612

Supplementary evidence received:
Letter from the Minister for Health and Social Services – Human Transplantation (Wales) Bill: Submission from Professor Fabre, 7 February 2013
Letter from the Minister for Health and Social Services – Human Transplantation (Wales) Bill: Emerging issues, 14 February 2013
Letter from the Minister for Health and Social Services – Human Transplantation (Wales) Bill: Issues from the final evidence session, 28 February 2013
Letter from the Minister for Health and Social Services – Human Transplantation (Wales) Bill: Communications campaign, 12 March 2013

Annexe B: Witnesses

571. The following witnesses provided oral evidence to the Committee on the dates noted below. Transcripts of all oral evidence sessions can be viewed in full at:

http://www.senedd.assemblywales.org/mgIssueHistoryHome.aspx?IId=1309

24 January 2013	
Lesley Griffiths AM	Member in Charge Minister for Health and Social Services
Roy Thomas	Kidney Wales Foundation
Sally Johnson	NHS Blood and Transplant
30 January 2013	
Dr Dariusz Tetla	Clinical Lead for Organ Donation, Cwm Taf Health Board
Professor Vivienne Harpwood	Chair of the Cwm Taf Organ Donation Committee
Dr Peter Matthews	Academy of Royal Colleges Wales
Dr Alan Clamp	Human Tissue Authority
Victoria Marshment	Human Tissue Authority
Chris Watson	British Transplantation Society
Sir Peter Simpson	UK Donation Ethics Committee
Dr Tim Lewens	Nuffield Council on Bioethics
Professor Ceri Phillips	
7 February 2013	
Joyce Robins	Patient Concern
Rev. Aled Edwards,	Cytûn-Churches Together in Wales and Inter-Faith Council for Wales
Geraint Hopkins	Cytûn-Churches Together in Wales
Saleem Kidwai	Muslim Council of Wales
Rev. Carol Wardman	Bishops' Adviser on Church and Society, Church in Wales

Stephen Wigley	Methodist Church in Wales
Professor John Saunders	
20 February 2013	
Phil Walton	Team Manager, Donor Care and Co-ordination, NHS Blood and Transplant
Lesley Griffiths AM	Member in Charge Minister for Health and Social Services